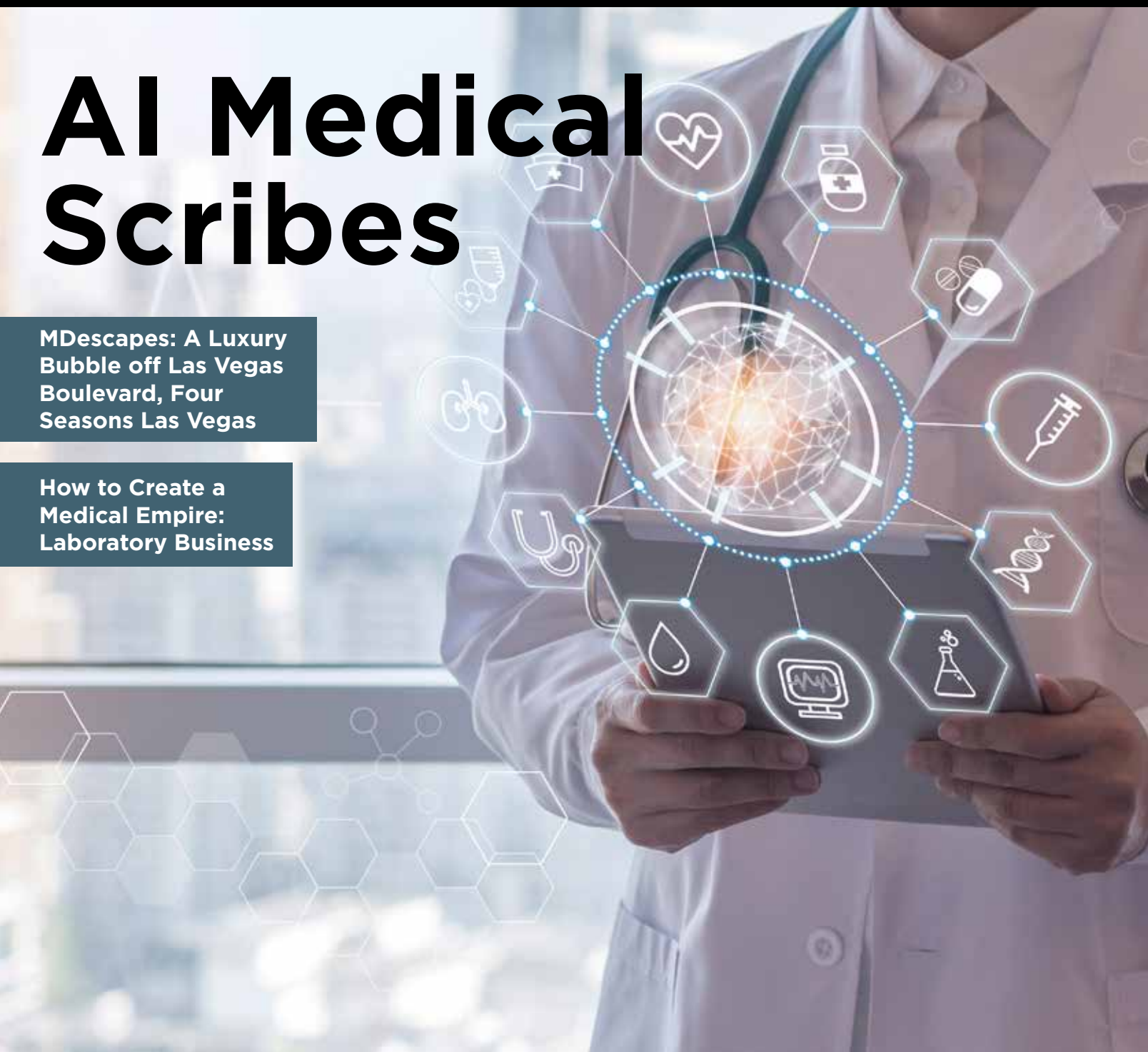
2024 | Issue 11

Physicians office Resource

Resources for You, Your Patients, & Your Practice



AI Medical Scribes

MDescapes: A Luxury Bubble off Las Vegas Boulevard, Four Seasons Las Vegas

How to Create a Medical Empire: Laboratory Business



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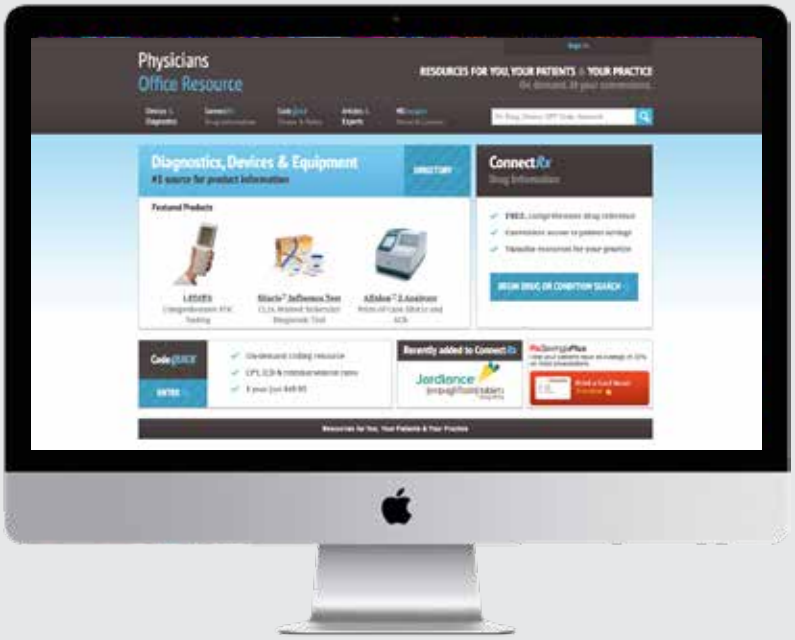
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PUBLISHED BY
Medical Education Resources, LLC

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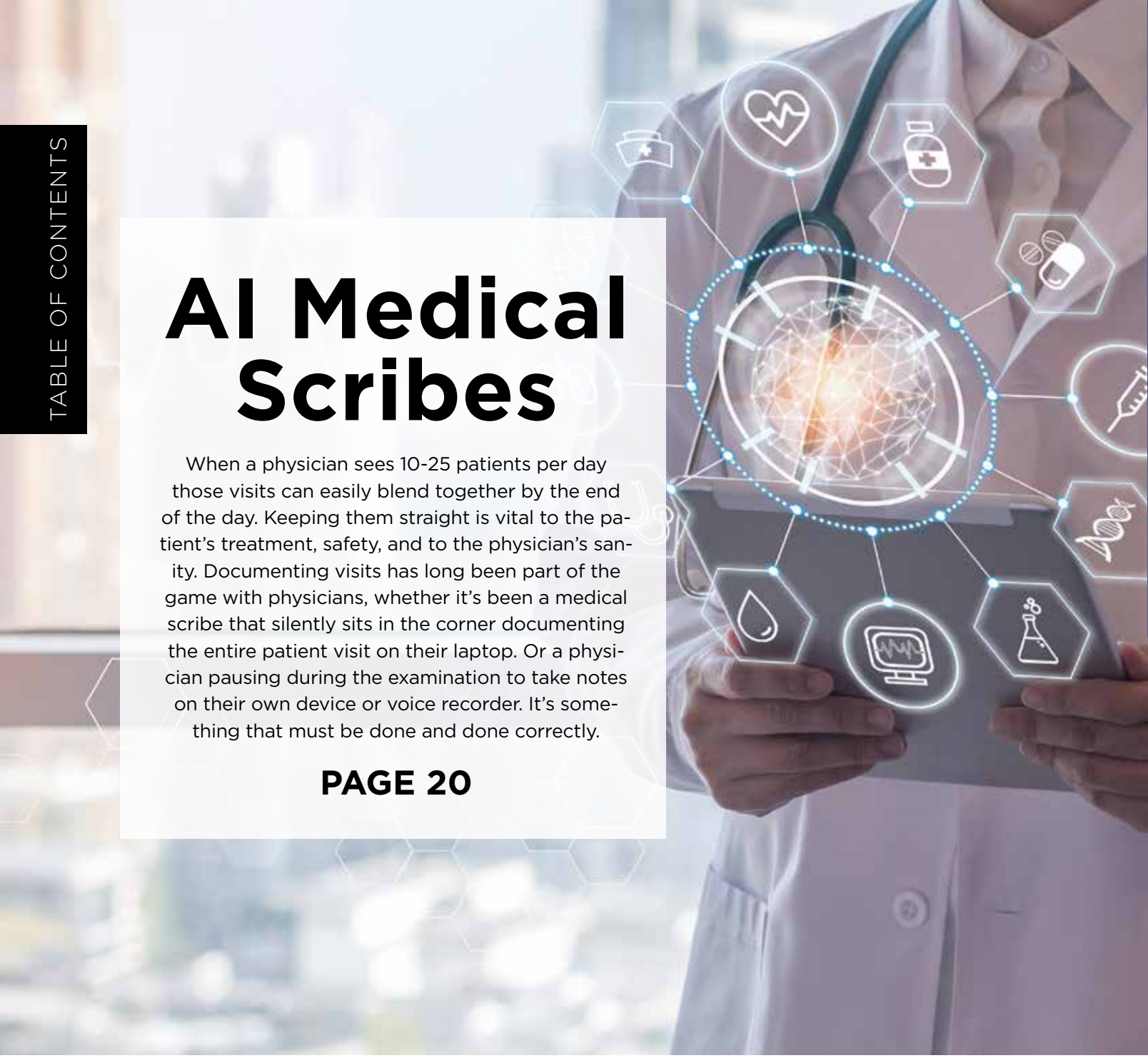
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AI Medical Scribes

When a physician sees 10-25 patients per day those visits can easily blend together by the end of the day. Keeping them straight is vital to the patient's treatment, safety, and to the physician's sanity. Documenting visits has long been part of the game with physicians, whether it's been a medical scribe that silently sits in the corner documenting the entire patient visit on their laptop. Or a physician pausing during the examination to take notes on their own device or voice recorder. It's something that must be done and done correctly.

PAGE 20

6

Part 6 of a 6 Part Series
How to Create a Medical Empire:
Laboratory Business

Entering the laboratory industry offers an exciting opportunity for healthcare professionals and investors alike, providing essential services to the medical field while also holding substantial financial promise.

32

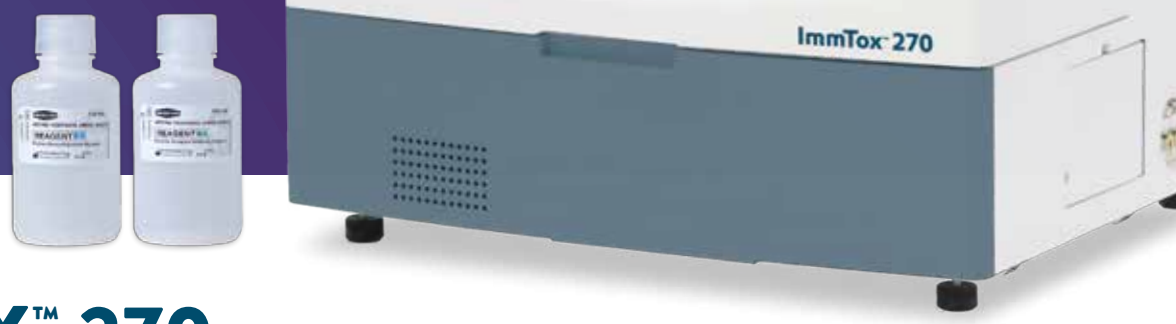
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PART 6 OF A 6 PART SERIES

HOW TO CREATE A MEDICAL EMPIRE:

Laboratory Business

BY DR. SHAKEEL AHMED

FOR PARTS 1-5 OF THIS SERIES PLEASE VISIT
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" The future belongs to those who believe in the beauty of their dreams."
— ELEANOR ROOSEVELT

Entering the laboratory industry offers an exciting opportunity for healthcare professionals and investors alike, providing essential services to the medical field while also holding substantial financial promise. With advancements in molecular diagnostics, the lab industry has seen consistent growth, driven by demand for specialized testing and precision medicine. However, success in this space requires not just clinical expertise but also a firm grasp of business fundamentals, regulatory requirements, and market trends. This article outlines the key considerations and challenges involved in building a successful diagnostic laboratory, from initial planning to long-term profitability, in a rapidly evolving healthcare landscape.

In my previous articles, I discussed investments in Multispecialty Groups, ASCs, Imaging Centers. The logical next addition to your portfolio is a medical lab. While an integrated practice-owned lab concept is an excellent investment for physicians, I want to focus in this article on a de novo freestanding lab concept for investors. The greatest benefit to the latter is a broader patient base. The disadvantage? Navigating the treacherous tracks of federal and state laws. Having said that, the laws and principles of the business apply to both setups.

Introduction

The American Clinical Laboratory Association (ACLA) is the national trade association of leading clinical laboratories. It renders essential information about diagnostic laboratories and their evolution to meet the nation's continuously evolving healthcare needs to patients and healthcare providers. The ACLA sees clinical laboratories as the first line of defense against disease, since all diseases inherently have identifiable factors that can be gleaned from the chemistry of blood and other fluids and the histology of tissue; such information spawns the ability to diagnose, and we'd be lost without it.

The ACLA, illuminating the critical role labs play in the healthcare system, states that diagnostic laboratories provide more than 70 percent of the medical information (knowledge) to diagnose and treat (action) patients. This is staggering when you consider how much additional (and crucial) information was provided by labs during the recent COVID-19 pandemic. Infectious agents, among many other culprits conspiring to do us in, are constantly changing. The pandemic adjustments to the sudden, unanticipated, and additional volume are just one example of how laboratories offer another advantage in the practice of medicine—they are designed to adapt.

Laboratories played a vital role in developing and distributing tests for COVID-19—in fact, providing the majority of the tests in the US. But COVID isn't entirely over; not yet. No one can guarantee a new variant or a wholly different infectious agent altogether won't rear its ugly head, making diagnostic labs our anchor in safe harbors.

Therefore, if you're looking to enter the laboratory business, this can be very lucrative financially; additionally, you can be reassured that the clinical laboratory world is expanding quickly. Since 2016, diagnostic and medical laboratories have grown by 1.5 percent yearly. It should continue at this rate (or faster) based on observable trends.

What Is Involved

CBCs, metabolic profiles, fasting glucose determination, Pap smears, and the other quotidian tests of yesteryear are now only afterthoughts in a brave new world of biochemistry and histology. Consider that it wasn't until 1984 that Helicobacter pylori (and not psychological stress) was associated with gastritis, with subsequent years of opportunities wasted due to a lack of credibility. One Nobel Prize later, H. pylori histological testing is mainstream in evaluating recalcitrant GERD and high GI cancer risk.

So, with total medical knowledge doubling every few months now, newly discovered epiphanies and complexities will continue to usher in ways to identify, quantify, and qualify illness. And treat them.

For example, molecular diagnostics, the process of identifying disease by studying the molecules in its cascade of determinants, such as proteins, DNA, and RNA in fluid or tissue, has skyrocketed due to the COVID-19 pandemic creating unprecedented demand for such testing. Also, advancements in precision medicine and genetics continue increasing demand. With the human genome project continually being raided for novel ways to address disease, the future of the diagnostic laboratory seems unbridled. While you may not be winning a Nobel Prize anytime soon, the academic and intellectual fascination will be nonstop. And—financially—stepping into the laboratory business is likely a sure bet if done right.

Do It Right

Besides walking hand-in-hand with a crucial piece of the modern diagnostic and treatment paradigm, owning a laboratory can be financially rewarding. The financial performance of diagnostic laboratories contributes significantly to our economy, generating $75 billion in revenue annually and employing over four hundred thousand people.

Physicians who consider such a venture should feel comfortable making such a rewarding and lucrative lateral move, considering they did well in their previous "box"; this portends well for doing well out of the box. Indeed, they already have a head start over other entrepreneurs because of their diagnostic sensibilities, education, and training. But that does not mean it isn't challenging—it is.

Even with the proper knowledge and resources, running a laboratory business can be complex and challenging, albeit rewarding and profitable. Laboratories play a fundamental role in the practice of medicine and provide critical diagnostic and analytical services to hospitals, clinics, and all other healthcare providers.

Create a Detailed Business Plan

This can steer you through the difficult questions before you start spending money or sweat equity over qualms about feasibility and profitability. A detailed business plan is useful for you and your potential investors. While it won't guarantee

the future, it will portend it reasonably well enough upon which to rely for making decisions.

According to the US Small Business Association (SBA.gov), a business plan will include:

- **The Executive Summary:** A brief overview of your lab, what it will do, and why it will do well. It should also include the business type. (Sole proprietorship, partnership, LLC, C-Corp, S-Corp? These considerations depend on your economic environment and what serves your financial plan best. This is probably advice you will have to pay for.)

- **Company Description:** An outline of what your lab will specialize in, what makes your lab unique (especially compared to your competitors), the advantages of your location, what needs you will fill, and all the positive aspects you can list.

- **Market Analysis:** The take on all the research into your competition.

- **Organization and Management:** Who will run the lab, how many employees will you hire, how many specialty tests and techs to support them, and how will it be managed?

- **Marketing and Sales:** Your plan to capture funding and sales and the marketing strategies you'll use to do this. How will you get into this market? How will you expand? What about communication and distribution?

- **Funding Requests:** How much will you need on the front end and during the transition from start-up to profitability? What will this funding cover? Why is the funding necessary?

- **Financial Projections:** This is the crux of your business plan—why and how you plan for the lab to be profitable, and the road to that time.

- **Appendix:** Your research sources.

Within your business plan will be the following additional considerations: How financially successful are the average labs in your area? How crowded is the marketplace you're seeking to enter? Have other labs required continued funding to be viable? Are there any special relationships with payers with whom you might have trouble contracting? These considerations take into account the networking milieu you'll be entering. Will you have more partnering associations than competitors (or, read another way, more allies than enemies)?

What is the market demand? Can you do the market research to make a legitimate case for getting into the lab business? There should be a competitive analysis. Are there competitors, and if so, can you do it better with newer technology? (Any lab already in business is already behind the times regarding technology.) Can you offer state-of-the-art technology for bragging rights that will give you a competitive advantage? Are there new cutting-edge technologies you want to feature? Are there new research and testing opportunities brewing, such as what emerged from the recent pandemic?

Who will be your customers? Learning this will be part of this research. This means knowing what products and services you will offer and how these will jive in the competitive marketplace. For example, do you want to invest in durable medical equipment to diagnose conditions specific to one demographic that is irrelevant to the demographics that predominate in your area? Do you want to cater to specialists from outpatient services, e.g., histology services for endoscopic biopsies, HPV testing, and reading colposcopy tissue biopsies for a large gynecology presence in the area?

Will there be customers you need from whom you'll be excluded contractually? Insurance panels are designed for several purposes, but none of those purposes are to benefit anyone but the insurers. Always keep that in mind. Nevertheless, networking potential is essential to learning who your customers will be.

Will you be competing with a large, nearby hospital? This requires extensive assessment of what you can offer to be done better, cheaper, or quicker.

Will your customers include those who favor online and delivery methods, e.g., stool samples, COVID-19 screening, genetic swabs, etc.? If so, will you have synchrony between your brick-and-mortar building and your online capabilities? This also includes the digital transfer of results to patients and providers alike.

Will your demographics be ethnically focused, age-specific, or predominate according to other considerations, such as gender? Will you be serving a particular niche?

Will a research grant strategy be a part of your plan? If so, in what way and under which funding possibilities?

What do data and statistics say about market demands, trends, and penetration?

These inquiries will answer issues over geographic realty trends, average labor costs, funding potential, and your competitors' state-of-the-art assets (or lack thereof). Pay for consultants to get you this information, because you'll have to commit to or decline this venture sooner or later and need the best information.

You need to know the costs of the reagents and media involved in your testing, the costs of the required equipment, and the employee salary costs.

If there are many competitors, will they adversely threaten the success of your lab? Remember that everything in this venture depends on supply and demand; even with competition, if demand is not completely supplied, there will be room for you. Thus, a competitor merely existing does not necessarily mean a struggle.

What about your other customers? By this, I mean your investors. Start-up labs require liquidity, so you must consider your investors as your other customers. Part of your business plan requires you to delineate project milestones that depend on product and service delivery. You also have to discuss cost-effective solutions such as rental of space, equipment, furniture, etc., vs. ownership, shared space, employee pools, and other ideas that can be explained as part of your anticipated return of investment.

Multiphase government research grants and direct sales of home testing over the internet will help control costs. Signing long-term customer contracts (including those other customers) is as important as the ones utilizing your services.

Buy (Sow)/Collect (Reap)

What type of lab you choose will determine the equipment and instrumentation you need to buy. For example, molecular diagnostics will be involved with the following:

1. DNA extraction
2. PCR machine/thermocycler
3. RT-PCR machine
4. Gel electrophoresis
5. DNA sequencing
6. Refrigerators/freezers
7. Buffers, gloves, tips, and other consumables
8. Any safety apparatus and other durable medical equipment and their supplies

Besides the cost of space (rental vs. amortization of purchase), incubators, refrigerators/freezers, computer systems (hardware and software), and furniture, most labs, generally, will need:

- microscopes
- hematology and differential counters, chemistry, blood gas, urine, DNA, and immunoassay analyzers
- autoclaves
- hotplates



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- histology and cytology equipment
- gamma counters
- microplate readers/washers
- point-of-care analyzers
- immunoassay analyzers
- hormonal testing
- cancer diagnosis and treatment biomarker testing
- hazard safety items, e.g., hoods, eyewash stations

Such equipment can range from $20,000 to $50,000.

The investment range of a small to medium lab can be from $38,000 to $200,000. However, this can anticipate a revenue potential of $350,000 to up to $1 million annually. Of course, the larger the lab, the bigger the numbers, not the least of which are the investment costs. On a positive note, the industry trend is excellent and growing. It has grown 3.1 percent annually in the last five years. As of 2023, more than thirty thousand diagnostic and medical labs were running in the United States.

Lab tests can cost anywhere from one hundred dollars to $1,000 or more, but for your purposes, they can be averaged as $300 per test. With all things applied, a 20 percent profit margin after overhead, space, and labor can be reasonably expected.

What Could Go Wrong?

The biggest challenge today for laboratories is a need for more qualified or certified employees, especially after the recent pandemic. The average lab technician has a bachelor's degree.

As a higher public and legislative sensitivity to medical waste continues, you can be sure there will be added costs to regulatory requirements in the future.

But keep in mind that our population is aging, expanding the industry by 24 percent in the last ten years. They will be getting older and more sizeable within the demographic cut of the pie.

Get Funding

Funding is no small part of the what-you-need formula. Different aspects of this are covered in other areas, but one beneficial tool is affiliating your lab with a grant. The federal government offers hundreds, funded by agencies such as the National Institutes of Health (NIH), the National Science Foundation (NSF), the Department of Energy (DOE), and more.

Article continued at
PhysiciansOfficeResource.com/articles



ABOUT THE AUTHOR:

Dr. Shakeel Ahmed

Spanning two decades, Dr. Shakeel Ahmed, a gastroenterologist turned healthcare mogul, has transformed his vision into the Midwest's leading Ambulatory Surgery Centers network. His dual expertise in medical administration and surgical execution-gained from years of frontline experience-has been pivotal in mastering the complexities of the healthcare sector. Dr. Ahmed's notable contributions extend beyond the ASC sphere; he has played a key role in developing a comprehensive healthcare network, including a range of medical facilities, diagnostic centers, and surgical establishments across several states. His literary contributions includes 6 published books alongside hundreds of articles in prestigious national and international journals. He is a consultant for multiple governments on healthcare development and works as an advisor to various governments across four continents in the establishment of outpatient surgery centers.

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1. Smolderen KG, Ameli O, Chaisson CE, Heath K, Mena-Hurtado C. Peripheral Artery Disease Screening in the Community and 1-Year Mortality, Cardiovascular Events, and Adverse Limb Events, AJPM Focus (2022), https://doi.org/10.1016/j.focus.2022.100016

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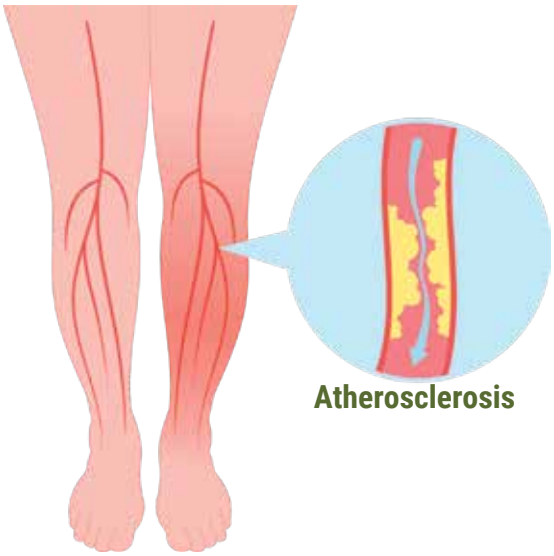
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acalabrutinib 100 mg tablets

UNPRECEDENTED PFS BENEFIT IN 1L CLL*‖

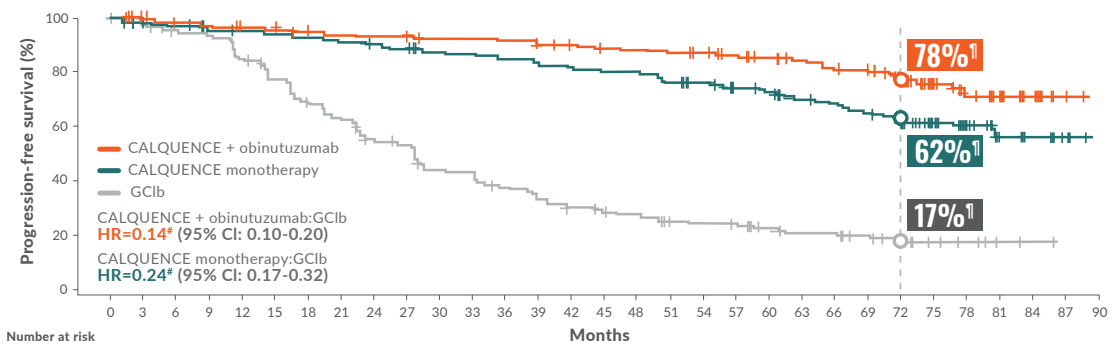
90% risk reduction in IRC-assessed disease progression or death (HR=0.10†; 95% CI: 0.06-0.17; *P*<0.0001‡) with CALQUENCE + obinutuzumab vs GClb and an **80% risk reduction** (HR=0.20†; 95% CI: 0.13-0.30; *P*<0.0001‡) with CALQUENCE monotherapy vs GClb at interim analysis (28.3-month median follow-up).[1]

6-YEAR FOLLOW-UP[2]

86% risk reduction in disease progression or death with CALQUENCE + obinutuzumab vs GClb at 74.5-month median follow-up§[2]

Median PFS not reached with CALQUENCE + obinutuzumab and was 27.8 months with GClb

Investigator-assessed PFS‖[2]



Number at risk																													
CALQUENCE + obinutuzumab	179	175	170	168	164	163	160	157	156	156	153	152	151	146	144	141	140	138	136	133	127	124	119	116	99	54	39	25	10	2	0
CALQUENCE monotherapy	179	167	163	158	156	155	153	150	149	146	142	141	137	135	133	130	129	124	121	115	113	103	100	95	85	56	37	22	7	2	0
GClb	177	163	156	153	139	125	110	100	86	82	67	66	56	49	44	41	38	30	29	28	24	21	21	18	14	8	6	3	1	0	0

*The primary outcome was IRC-assessed PFS for CALQUENCE + obinutuzumab vs GClb.[1]

†Based on a stratified Cox-Proportional-Hazards model. Both HRs are compared with the GClb arm.[1]

‡Based on a stratified log-rank test, with an alpha level of 0.012 derived from alpha spending function by the O'Brien-Fleming method.[1]

§Range: 0.0-89.0 months.[2]

‖After the interim analysis at 28.3-month median follow-up, PFS was INV-assessed only.[2]

¶Estimated PFS rate at 72 months.[2]

#HR based on stratified Cox-Proportional-Hazards model.[2]

CI= Confidence Interval; CLL=chronic lymphocytic leukemia; GClb=obinutuzumab + chlorambucil; HR=hazard ratio; INV=investigator; IRC=Independent Review Committee; PFS=progression-free survival.

The 74.5-month median follow-up data from ELEVATE-TN are not in the Prescribing Information for CALQUENCE. The timing for long-term follow-up was not prespecified, and the analysis was descriptive in nature.

INDICATION AND USAGE

CALQUENCE is a Bruton tyrosine kinase (BTK) inhibitor indicated for the treatment of adult patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL).

IMPORTANT SAFETY INFORMATION ABOUT CALQUENCE® (acalabrutinib) tablets

Serious and Opportunistic Infections

Fatal and serious infections, including opportunistic infections, have occurred in patients with hematologic malignancies treated with CALQUENCE.

Serious or Grade 3 or higher infections (bacterial, viral, or fungal) occurred in 19% of 1029 patients exposed to CALQUENCE in clinical trials, most often due to respiratory tract infections (11% of all patients, including pneumonia in 6%). These infections predominantly occurred in the absence of Grade 3 or 4 neutropenia, with neutropenic infection reported in 1.9% of all patients. Opportunistic infections in recipients of CALQUENCE have included, but are not limited to, hepatitis B virus reactivation, fungal pneumonia, *Pneumocystis jirovecii* pneumonia, Epstein-Barr virus reactivation, cytomegalovirus, and progressive multifocal leukoencephalopathy (PML). Consider prophylaxis in patients who are at increased risk for opportunistic infections. Monitor patients for signs and symptoms of infection and treat promptly.

Hemorrhage

Fatal and serious hemorrhagic events have occurred in patients with hematologic malignancies treated with CALQUENCE. Major hemorrhage (serious or Grade 3 or higher bleeding or any central nervous system bleeding) occurred in 3.0% of patients, with fatal hemorrhage occurring in 0.1% of 1029 patients exposed to CALQUENCE in clinical trials. Bleeding events of any grade, excluding bruising and petechiae, occurred in 22% of patients.

Use of antithrombotic agents concomitantly with CALQUENCE may further increase the risk of hemorrhage. In clinical trials, major hemorrhage occurred in 2.7% of patients taking CALQUENCE without antithrombotic agents and 3.6% of patients taking CALQUENCE with antithrombotic agents. Consider the risks and benefits of antithrombotic agents when co-administered with CALQUENCE. Monitor patients for signs of bleeding.

Consider the benefit-risk of withholding CALQUENCE for 3-7 days pre- and post-surgery depending upon the type of surgery and the risk of bleeding.

Cytopenias

Grade 3 or 4 cytopenias, including neutropenia (23%), anemia (8%), thrombocytopenia (7%), and lymphopenia (7%), developed in patients with hematologic malignancies treated with CALQUENCE. Grade 4 neutropenia developed in 12% of patients. Monitor complete blood counts regularly during treatment. Interrupt treatment, reduce the dose, or discontinue treatment as warranted.

Second Primary Malignancies

Second primary malignancies, including skin cancers and other solid tumors, occurred in 12% of 1029 patients exposed to CALQUENCE in clinical trials. The most frequent second primary malignancy was skin cancer, reported in 6% of patients. Monitor patients for skin cancers and advise protection from sun exposure.

Cardiac Arrhythmias

Serious cardiac arrhythmias have occurred in patients treated with CALQUENCE. Grade 3 atrial fibrillation or flutter occurred in 1.1% of 1029 patients treated with CALQUENCE, with all grades of atrial fibrillation or flutter reported in 4.1% of all patients. Grade 3 or higher ventricular arrhythmia events were reported in 0.9% of patients. The risk may be increased in patients with cardiac risk factors, hypertension, previous arrhythmias, and acute infection. Monitor for symptoms of arrhythmia (eg, palpitations, dizziness, syncope, dyspnea) and manage as appropriate.

Hepatotoxicity, Including Drug-Induced Liver Injury

Hepatotoxicity, including severe, life-threatening, and potentially fatal cases of drug-induced liver injury (DILI), has occurred in patients treated with Bruton tyrosine kinase inhibitors, including CALQUENCE.

Evaluate bilirubin and transaminases at baseline and throughout treatment with CALQUENCE. For patients who develop abnormal liver tests after CALQUENCE, monitor more frequently for liver test abnormalities and clinical signs and symptoms of hepatic toxicity. If DILI is suspected, withhold CALQUENCE. Upon confirmation of DILI, discontinue CALQUENCE.

ELEVATE-TN: 1L CLL

6-YEAR FOLLOW-UP[2]

Events of clinical interest at 74.5-month median follow-up were consistent with the established profile of CALQUENCE[2]

Events of clinical interest[2]

	CALQUENCE + obinutuzumab (n=178)		CALQUENCE monotherapy (n=179)	
	Any Grade (%)	Grade ≥3 (%)	Any Grade (%)	Grade ≥3 (%)
Cardiac events	28	12	24	12
Atrial fibrillation	7	1.7	9	1.7
Bleeding	53	7	45	4.5
Major bleeding*	9	7	6	4.5
Hypertension	11	4.5	11	5
Infections	83	35	80	28
Second primary malignancy (SPM)	20	10	20	5
SPMs excluding non-melanoma skin cancers	14	7	12	3.9

*Defined as any serious or Grade ≥3 hemorrhagic event, or any grade hemorrhagic event in the central nervous system.[3]

Median duration of exposure was 74.4 months with CALQUENCE + obinutuzumab and 72.0 months with CALQUENCE monotherapy.[2]

The 74.5-month median follow-up data from ELEVATE-TN are not in the Prescribing Information for CALQUENCE.

At 28.3-month median follow-up:

- The most common ARs (≥30%) of any grade in patients treated with CALQUENCE + obinutuzumab (n=178) were infection (69%), neutropenia (53%), anemia (52%), thrombocytopenia (51%), headache (40%), diarrhea (39%), musculoskeletal pain (37%), fatigue (34%), and bruising (31%). In the CALQUENCE monotherapy arm (n=179), the most common ARs (≥30%) of any grade were infection (65%), anemia (53%), headache (39%), diarrhea (35%), musculoskeletal pain (32%), and thrombocytopenia (32%). The median duration of exposure with CALQUENCE + obinutuzumab was 27.7 months and CALQUENCE monotherapy was 27.7 months. Safety and tolerability results at 74.5-month median follow-up in ELEVATE-TN were consistent with the interim analysis.[†1,2]

ELEVATE-TN Study Design: Phase 3, open-label, randomized, multicenter trial in 535 patients with previously untreated CLL evaluating CALQUENCE ± obinutuzumab vs GClb. Patients were randomized 1:1:1 to receive either CALQUENCE + obinutuzumab (n=179), CALQUENCE monotherapy (n=179), or obinutuzumab + chlorambucil (maximum 6 cycles; n=177). Patients received CALQUENCE 100 mg orally approximately every 12 hours until disease progression or unacceptable toxicity for either CALQUENCE + obinutuzumab or CALQUENCE monotherapy. The primary endpoint was IRC-assessed PFS for CALQUENCE + obinutuzumab vs GClb. After the interim analysis at 28.3-month median follow-up, PFS was INV-assessed only. Select secondary endpoints at interim analysis were IRC-assessed PFS (CALQUENCE monotherapy vs GClb), IRC-assessed ORR, OS, and safety. After the interim analysis of 28.3 months, PFS and ORR were INV-assessed only.[1,2]

1L=first line; AR=adverse reaction; ORR=overall response rate; OS=overall survival.

IMPORTANT SAFETY INFORMATION (cont'd)

ADVERSE REACTIONS

The most common adverse reactions (≥30%) of any grade in patients with CLL were anemia,* neutropenia,* thrombocytopenia,* headache, upper respiratory tract infection, and diarrhea.

*Treatment-emergent decreases (all grades) of hemoglobin, platelets, and neutrophils were based on laboratory measurements and adverse reactions.

In patients with previously untreated CLL exposed to CALQUENCE, fatal adverse reactions that occurred in the absence of disease progression and with onset within 30 days of the last study treatment were reported in 2% for each treatment arm, most often from infection. Serious adverse reactions were reported in 39% of patients in the CALQUENCE plus obinutuzumab arm and 32% in the CALQUENCE monotherapy arm, most often due to events of pneumonia (7% and 2.8%, respectively).

Adverse reactions led to CALQUENCE dose reduction in 7% and 4% of patients in the CALQUENCE plus obinutuzumab arm (N=178) and CALQUENCE monotherapy arm (N=179), respectively. Adverse events led to discontinuation in 11% and 10% of patients, respectively. Increases in creatinine to 1.5 to 3 times the upper limit of normal (ULN) occurred in 3.9% and 2.8% of patients in the CALQUENCE combination arm and monotherapy arm, respectively.

In patients with relapsed/refractory CLL exposed to CALQUENCE, serious adverse reactions occurred in 29% of patients. Serious adverse reactions in >5% of patients who received CALQUENCE included lower respiratory tract infection (6%). Fatal adverse reactions within 30 days of the last dose of CALQUENCE occurred in 2.6% of patients, including from second primary malignancies and infection.

Adverse reactions led to CALQUENCE dose reduction in 3.9% of patients (N=154), dose interruptions in 34% of patients, most often due to respiratory tract infections followed by neutropenia, and discontinuation in 10% of patients, most frequently due to second primary malignancies followed by infection. Increases in creatinine to 1.5 to 3 times ULN occurred in 1.3% of patients who received CALQUENCE.

DRUG INTERACTIONS

Strong CYP3A Inhibitors: Avoid co-administration of CALQUENCE with a strong CYP3A inhibitor. If these inhibitors will be used short-term, interrupt CALQUENCE. After discontinuation of strong CYP3A inhibitor for at least 24 hours, resume previous dosage of CALQUENCE.

Moderate CYP3A Inhibitors: Reduce the dosage of CALQUENCE to 100 mg once daily when co-administered with a moderate CYP3A inhibitor.

Strong CYP3A Inducers: Avoid co-administration of CALQUENCE with a strong CYP3A inducer. If co-administration is unavoidable, increase the dosage of CALQUENCE to 200 mg approximately every 12 hours.

SPECIFIC POPULATIONS

Based on findings in animals, CALQUENCE may cause fetal harm and dystocia when administered to a pregnant woman. There are no available data in pregnant women to inform the drug-associated risk. Advise pregnant women of the potential risk to a fetus.

Pregnancy testing is recommended for females of reproductive potential prior to initiating CALQUENCE therapy. Advise female patients of reproductive potential to use effective contraception during treatment with CALQUENCE and for 1 week following the last dose of CALQUENCE.

It is not known if CALQUENCE is present in human milk. Advise lactating women not to breastfeed while taking CALQUENCE and for 2 weeks after the last dose.

Avoid use of CALQUENCE in patients with severe hepatic impairment (Child-Pugh class C). No dosage adjustment of CALQUENCE is recommended in patients with mild (Child-Pugh class A) or moderate (Child-Pugh class B) hepatic impairment.

Please see Brief Summary of full Prescribing Information on adjacent pages.

You are encouraged to report the negative side effects of prescription drugs to the FDA. Visit www.FDA.gov/medwatch or call 1-800-FDA-1088.

References: 1. CALQUENCE® (acalabrutinib) tablets [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; 2024. **2.** Sharman JP, Egyed M, Jurczak W, et al. Acalabrutinib ± obinutuzumab vs obinutuzumab + chlorambucil in treatment-naive chronic lymphocytic leukemia: 6-year follow-up of ELEVATE-TN. Abstract presented at: American Society of Hematology (ASH) Annual Meeting; December 9-12, 2023; San Diego, CA. Abs 636. **3.** Sharman JP, Egyed M, Jurczak W, et al. Acalabrutinib with or without obinutuzumab versus chlorambucil and obinutuzumab for treatment-naive chronic lymphocytic leukaemia (ELEVATE-TN): a randomised, controlled, phase 3 trial [published correction appears in *Lancet*. 2020;395(10238):1694].

[†]Apart from COVID-19, which was observed during the pandemic.[2]

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AstraZeneca

CALQUENCE® (acalabrutinib) tablets, for oral use
Initial U.S. Approval: 2017

Brief Summary of Prescribing Information.
For full Prescribing Information consult official package insert.

INDICATIONS AND USAGE

Chronic Lymphocytic Leukemia or Small Lymphocytic Lymphoma

CALQUENCE is indicated for the treatment of adult patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL).

DOSAGE AND ADMINISTRATION

Recommended Dosage

CALQUENCE as Monotherapy

For patients with CLL, or SLL, the recommended dosage of CALQUENCE is 100 mg taken orally approximately every 12 hours until disease progression or unacceptable toxicity.

CALQUENCE in Combination with Obinutuzumab

For patients with previously untreated CLL or SLL, the recommended dosage of CALQUENCE is 100 mg taken orally approximately every 12 hours until disease progression or unacceptable toxicity. Start CALQUENCE at Cycle 1 (each cycle is 28 days). Start obinutuzumab at Cycle 2 for a total of 6 cycles and refer to the obinutuzumab prescribing information for recommended dosing. Administer CALQUENCE prior to obinutuzumab when given on the same day.

Advise patients to swallow tablet whole with water. Advise patients not to chew, crush, dissolve, or cut the tablets. CALQUENCE may be taken with or without food. If a dose of CALQUENCE is missed by more than 3 hours, it should be skipped and the next dose should be taken at its regularly scheduled time. Extra tablets of CALQUENCE should not be taken to make up for a missed dose.

Recommended Dosage for Drug Interactions

Dosage Modifications for Use with CYP3A Inhibitors or Inducers

These are described in Table 1 *[see Drug Interactions (7) in the full Prescribing Information]*.

Table 1: Recommended Dosage Modifications for Use with CYP3A Inhibitors or Inducers

CYP3A	Co-administered Drug	Recommended CALQUENCE use
Inhibition	Strong CYP3A inhibitor	Avoid co-administration. If these inhibitors will be used short-term (such as anti-infectives for up to seven days), interrupt CALQUENCE. After discontinuation of strong CYP3A inhibitor for at least 24 hours, resume previous dosage of CALQUENCE.
	Moderate CYP3A inhibitor	Reduce the CALQUENCE 100 mg every 12 hours dosage to 100 mg once daily.
Induction	Strong CYP3A inducer	Avoid co-administration. If co-administration is unavoidable, increase CALQUENCE dosage to 200 mg approximately every 12 hours.

Dosage Modifications for Adverse Reactions

Recommended dosage modifications of CALQUENCE for Grade 3 or greater adverse reactions are provided in Table 2.

Table 2: Recommended Dosage Modifications for Adverse Reactions

Event	Adverse Reaction Occurrence	Dosage Modification (Starting dose = 100 mg approximately every 12 hours)
Grade 3 or greater non-hematologic toxicities, Grade 3 thrombocytopenia with bleeding, Grade 4 thrombocytopenia or Grade 4 neutropenia lasting longer than 7 days	First and Second	Interrupt CALQUENCE. Once toxicity has resolved to Grade 1 or baseline level, CALQUENCE may be resumed at 100 mg approximately every 12 hours.
	Third	Interrupt CALQUENCE. Once toxicity has resolved to Grade 1 or baseline level, CALQUENCE may be resumed at a reduced frequency of 100 mg once daily.
	Fourth	Discontinue CALQUENCE.

Adverse reactions graded by the National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE).

Refer to the obinutuzumab prescribing information for management of obinutuzumab toxicities.

CONTRAINDICATIONS

None.

WARNINGS AND PRECAUTIONS

Serious and Opportunistic Infections

Fatal and serious infections, including opportunistic infections, have occurred in patients with hematologic malignancies treated with CALQUENCE.

Serious or Grade 3 or higher infections (bacterial, viral, or fungal) occurred in 19% of 1029 patients exposed to CALQUENCE in clinical trials, most often due to respiratory tract infections (11% of all patients, including pneumonia in 6%) *[see Adverse Reactions (6.1) in the full Prescribing Information]*. These infections predominantly occurred in the absence of Grade 3 or 4 neutropenia, with neutropenic infection reported in 1.9% of all patients. Opportunistic infections in recipients of CALQUENCE have included, but are not limited to, hepatitis B virus reactivation, fungal pneumonia, *Pneumocystis jirovecii* pneumonia, Epstein-Barr virus reactivation, cytomegalovirus, and progressive multifocal leukoencephalopathy (PML). Consider prophylaxis in patients who are at increased risk for opportunistic infections. Monitor patients for signs and symptoms of infection and treat promptly.

Hemorrhage

Fatal and serious hemorrhagic events have occurred in patients with hematologic malignancies treated with CALQUENCE. Major hemorrhage (serious or Grade 3 or higher bleeding or any central nervous system bleeding) occurred in 3.0% of patients, with fatal hemorrhage occurring in 0.1% of 1029 patients exposed to CALQUENCE in clinical trials. Bleeding events of any grade, excluding bruising and petechiae, occurred in 22% of patients *[see Adverse Reactions (6.1) in the full Prescribing Information]*.

Use of antithrombotic agents concomitantly with CALQUENCE may further increase the risk of hemorrhage. In clinical trials, major hemorrhage occurred in 2.7% of patients taking CALQUENCE without antithrombotic agents and 3.6% of patients taking CALQUENCE with antithrombotic agents. Consider the risks and benefits of antithrombotic agents when co-administered with CALQUENCE. Monitor patients for signs of bleeding.

Consider the benefit-risk of withholding CALQUENCE for 3 to 7 days pre- and post-surgery depending upon the type of surgery and the risk of bleeding.

Cytopenias

Grade 3 or 4 cytopenias, including neutropenia (23%), anemia (8%), thrombocytopenia (7%), and lymphopenia (7%), developed in patients with hematologic malignancies treated with CALQUENCE. Grade 4 neutropenia developed in 12% of patients *[see Adverse Reactions (6.1) in the full Prescribing Information]*. Monitor complete blood counts regularly during treatment. Interrupt treatment, reduce the dose, or discontinue treatment as warranted *[see Dosage and Administration (2.3) in the full Prescribing Information]*.

Second Primary Malignancies

Second primary malignancies, including skin cancers and other solid tumors, occurred in 12% of 1029 patients exposed to CALQUENCE in clinical trials *[see Adverse Reactions (6.1) in the full Prescribing Information]*. The most frequent second primary malignancy was skin cancer, reported in 6% of patients. Monitor patients for skin cancers and advise protection from sun exposure.

Cardiac Arrhythmias

Serious cardiac arrhythmias have occurred in patients treated with CALQUENCE. Grade 3 atrial fibrillation or flutter occurred in 1.1% of 1029 patients treated with CALQUENCE, with all grades of atrial fibrillation or flutter reported in 4.1% of all patients *[see Adverse Reactions (6.1) in the full Prescribing Information]*. Grade 3 or higher ventricular arrhythmia events were reported in 0.9% of patients. The risk may be increased in patients with cardiac risk factors, hypertension, previous arrhythmias, and acute infection. Monitor for symptoms of arrhythmia (e.g., palpitations, dizziness, syncope, dyspnea) and manage as appropriate.

Hepatotoxicity, Including Drug-Induced Liver Injury

Hepatotoxicity, including severe, life-threatening, and potentially fatal cases of drug-induced liver injury (DILI), has occurred in patients treated with Bruton tyrosine kinase inhibitors, including CALQUENCE.

Evaluate bilirubin and transaminases at baseline and throughout treatment with CALQUENCE. For patients who develop abnormal liver tests after CALQUENCE, monitor more frequently for liver test abnormalities and clinical signs and symptoms of hepatic toxicity. If DILI is suspected, withhold CALQUENCE. Upon confirmation of DILI, discontinue CALQUENCE.

ADVERSE REACTIONS

The following clinically significant adverse reactions are discussed in greater detail in other sections of the labeling:

- Serious and Opportunistic Infections *[see Warnings and Precautions (5.1) in the full Prescribing Information]*
- Hemorrhage *[see Warnings and Precautions (5.2) in the full Prescribing Information]*
- Cytopenias *[see Warnings and Precautions (5.3) in the full Prescribing Information]*
- Second Primary Malignancies *[see Warnings and Precautions (5.4) in the full Prescribing Information]*
- Cardiac Arrhythmias *[see Warnings and Precautions (5.5) in the full Prescribing Information]*
- Hepatotoxicity, including DILI *[see Warnings and Precautions (5.6) in the full Prescribing Information]*

Clinical Trials Experience

As clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

The data in the Warnings and Precautions reflect exposure to CALQUENCE 100 mg approximately every 12 hours in 1029 patients with hematologic malignancies. Treatment includes CALQUENCE monotherapy in 820 patients in 6 trials, and CALQUENCE with obinutuzumab in 209 patients in 2 trials. Among these recipients of CALQUENCE, 88% were exposed for at least 6 months and 79% were exposed for at least one year. In this pooled safety population, adverse reactions in ≥ 30% of 1029 patients were anemia, neutropenia, upper respiratory tract infection, thrombocytopenia, headache, diarrhea, and musculoskeletal pain.

Chronic Lymphocytic Leukemia

The safety data described below reflect exposure to CALQUENCE (100 mg approximately every 12 hours, with or without obinutuzumab) in 511 patients with CLL from two randomized controlled clinical trials *[see Clinical Studies (14.2) in the full Prescribing Information]*.

The most common adverse reactions (≥ 30%) of any grade in patients with CLL were anemia, neutropenia, thrombocytopenia, headache, upper respiratory tract infection, and diarrhea.

ELEVATE-TN

The safety of CALQUENCE plus obinutuzumab (CALQUENCE+G), CALQUENCE monotherapy, and obinutuzumab plus chlorambucil (GClb) was evaluated in a randomized, multicenter, open-label, actively controlled trial in 526 patients with previously untreated CLL *[see Clinical Studies (14.2) in the full Prescribing Information]*.

Patients randomized to the CALQUENCE+G arm were treated with CALQUENCE and obinutuzumab in combination for six cycles, then with CALQUENCE as monotherapy until disease progression or unacceptable toxicity. Patients initiated obinutuzumab on Day 1 of Cycle 2, continuing for a total of 6 cycles. Patient randomized to CALQUENCE monotherapy received CALQUENCE approximately every 12 hours until disease progression or unacceptable toxicity. The trial required age ≥ 65 years of age or 18 to < 65 years of age with a total Cumulative Illness Rating Scale (CIRS) > 6 or creatinine clearance of 30 to 69 mL/min, hepatic transaminases ≤ 3 times ULN and total bilirubin ≤1.5 times ULN, and allowed patients to receive antithrombotic agents other than warfarin or equivalent vitamin K antagonists.

During randomized treatment, the median duration of exposure to CALQUENCE in the CALQUENCE+G and CALQUENCE monotherapy arms was 27.7 months (range 0.3 to 40 months), with 95% and 92% and 89% and 86% of patients with at least 6 months and 12 months of exposure, respectively. In the obinutuzumab and chlorambucil arm the median number of cycles was 6 with 84% of patients receiving at least 6 cycles of obinutuzumab, 70% of patients received at least 6 cycles of chlorambucil. Eighty-five percent of patients in the CALQUENCE+G arm received at least 6 cycles of obinutuzumab.

In the CALQUENCE+G and CALQUENCE monotherapy arms, fatal adverse reactions that occurred in the absence of disease progression and with onset within 30 days of the last study treatment were reported in 2% for each treatment arm, most often from infection. Serious adverse reactions were reported in 39% of patients in the CALQUENCE+G arm and 32% in the CALQUENCE monotherapy arm, most often due to events of pneumonia (2.8% to 7%).

In the CALQUENCE+G arm, adverse reactions led to treatment discontinuation in 11% of patients and a dose reduction of CALQUENCE in 7% of patients. In the CALQUENCE monotherapy arm, adverse reactions led to discontinuation in 10% and dose reduction in 4% of patients.

Tables 5 and 6 present adverse reactions and laboratory abnormalities identified in the ELEVATE-TN trial.

Table 5: Common Adverse Reactions (≥ 15% Any Grade) with CALQUENCE in Patients with CLL (ELEVATE-TN)

Body System Adverse Reaction*	CALQUENCE plus Obinutuzumab N=178		CALQUENCE Monotherapy N=179		Obinutuzumab plus Chlorambucil N=169	
	All Grades (%)	Grade ≥ 3 (%)	All Grades (%)	Grade ≥ 3 (%)	All Grades (%)	Grade ≥ 3 (%)
Infections						
Infection[†]	69	22[‡]	65	14[‡]	46	13[‡]
Upper respiratory tract infection[§]	39	2.8	35	0	17	1.2
Lower respiratory tract infection[¶]	24	8	18	4.5	7	1.8
Urinary tract infection	15	1.7	15	2.8	5	0.6
Blood and lymphatic system disorders[#]						
Neutropenia[£]	53	37	23	13	78	50
Anemia[¤]	52	12	53	10	54	14
Thrombocytopenia[¥]	51	12	32	3.4	61	16
Lymphocytosis[†]	12	11	16	15	0.6	0.6
Nervous system disorders						
Headache	40	1.1	39	1.1	12	0
Dizziness	20	0	12	0	7	0
Gastrointestinal disorders						
Diarrhea	39	4.5	35	0.6	21	1.8
Nausea	20	0	22	0	31	0
Musculoskeletal and connective tissue disorders						
Musculoskeletal pain[§]	37	2.2	32	1.1	16	2.4
Arthralgia	22	1.1	16	0.6	4.7	1.2
General disorders and administration site conditions						
Fatigue[¶]	34	2.2	23	1.1	24	1.2
Skin and subcutaneous tissue disorders						
Bruising[†]	31	0	21	0	5	0
Rash[‡]	26	2.2	25	0.6	9	0.6
Vascular disorders						
Hemorrhage[¥]	20	1.7	20	1.7	6	0

* Per NCI CTCAE version 4.03

† Includes any adverse reactions involving infection or febrile neutropenia
‡ Includes 3 fatal cases in the CALQUENCE plus obinutuzumab arm, 3 fatal cases in the CALQUENCE monotherapy arm and 1 fatal case in the obinutuzumab plus chlorambucil arm
§ Includes upper respiratory tract infection, nasopharyngitis and sinusitis
[a] Includes pneumonia, lower respiratory tract infection, bronchitis, bronchiolitis, tracheitis, and lung infection
[b] Derived from adverse reaction and laboratory data
[c] Includes neutropenia, neutrophil count decreased, and related laboratory data
[d] Includes anemia, red blood cell count decreased, and related laboratory data
[e] Includes thrombocytopenia, platelet count decreased, and related laboratory data
[f] Includes lymphocytosis, lymphocyte count increased, and related laboratory data
[g] Includes back pain, bone pain, musculoskeletal chest pain, musculoskeletal pain, musculoskeletal discomfort, myalgia, neck pain, pain in extremity and spinal pain
[h] Includes asthenia, fatigue, and lethargy
[i] Includes bruise, contusion, and ecchymosis
[j] Includes rash, dermatitis, and other related terms
[k] Includes hemorrhage, hematoma, hemoptysis, hematuria, menorrhagia, hemarthrosis, and epistaxis

Other clinically relevant adverse reactions (all grades incidence < 15%) in recipients of CALQUENCE (CALQUENCE in combination with obinutuzumab and monotherapy) included:

- *Neoplasms:* second primary malignancy (10%), non-melanoma skin cancer (5%)
- *Cardiac disorders:* atrial fibrillation or flutter (3.6%), hypertension (5%)
- *Infection:* herpesvirus infection (6%)

Table 6: Select Non-Hematologic Laboratory Abnormalities (≥ 15% Any Grade), New or Worsening from Baseline in Patients Receiving CALQUENCE (ELEVATE-TN)

Laboratory Abnormality*, [a]	CALQUENCE plus Obinutuzumab N=178		CALQUENCE Monotherapy N=179		Obinutuzumab plus Chlorambucil N=169	
	All Grades (%)	Grade ≥ 3 (%)	All Grades (%)	Grade ≥ 3 (%)	All Grades (%)	Grade ≥ 3 (%)
Uric acid increase	29	29	22	22	37	37
ALT increase	30	7	20	1.1	36	6
AST increase	38	5	17	0.6	60	8
Bilirubin increase	13	0.6	15	0.6	11	0.6

*Per NCI CTCAE version 4.03
[a] Excludes electrolytes

Increases in creatinine to 1.5 to 3 times ULN occurred in 3.9% and 2.8% of patients in the CALQUENCE combination arm and monotherapy arm, respectively.

ASCEND

The safety of CALQUENCE in patients with relapsed or refractory CLL was evaluated in a randomized, open-label study (ASCEND) *[see Clinical Studies (14.2) in the full Prescribing Information]*. The trial enrolled patients with relapsed or refractory CLL after at least one prior therapy and required hepatic transaminases ≤ 2 times ULN, total bilirubin ≤ 1.5 times ULN, and an estimated creatinine clearance ≥ 30 mL/min. The trial excluded patients having an absolute neutrophil count < 500/µL, platelet count < 30,000/µL, prothrombin time or activated partial thromboplastin time > 2 times ULN, significant cardiovascular disease, or a requirement for strong CYP3A inhibitors or inducers. Patients were allowed to receive antithrombotic agents other than warfarin or equivalent vitamin K antagonist.

In ASCEND, 154 patients received CALQUENCE (100 mg approximately every 12 hours until disease progression or unacceptable toxicity), 118 received idelalisib (150 mg approximately every 12 hours until disease progression or unacceptable toxicity) with up to 8 infusions of a rituximab product, and 35 received up to 6 cycles of bendamustine and a rituximab product. The median age overall was 68 years (range: 32-90); 67% were male; 92% were white; and 88% had an ECOG performance status of 0 or 1.

In the CALQUENCE arm, serious adverse reactions occurred in 29% of patients. Serious adverse reactions in > 5% of patients who received CALQUENCE included lower respiratory tract infection (6%). Fatal adverse reactions within 30 days of the last dose of CALQUENCE occurred in 2.6% of patients, including from second primary malignancies and infection.

In recipients of CALQUENCE, permanent discontinuation due to an adverse reaction occurred in 10% of patients, most frequently due to second primary malignancies followed by infection. Adverse reactions led to dosage interruptions of CALQUENCE in 34% of patients, most often due to respiratory tract infections followed by neutropenia, and dose reduction in 3.9% of patients.

Selected adverse reactions are described in Table 7 and non-hematologic laboratory abnormalities are described in Table 8. These tables reflect exposure to CALQUENCE with median duration of 15.7 months with 94% of patients on treatment for greater than 6 months and 86% of patients on treatment for greater than 12 months. The median duration of exposure to idelalisib was 11.5 months with 72% of patients on treatment for greater than 6 months and 48% of patients on treatment for greater than 12 months. Eighty-three percent of patients completed 6 cycles of bendamustine and rituximab product.

Table 7: Common Adverse Reactions (≥ 15% Any Grade) with CALQUENCE in Patients with CLL (ASCEND)

Body System Adverse Reaction*	CALQUENCE N=154		Idelalisib plus Rituximab Product N=118		Bendamustine plus Rituximab Product N=35	
	All Grades (%)	Grade ≥ 3 (%)	All Grades (%)	Grade ≥ 3 (%)	All Grades (%)	Grade ≥ 3 (%)
Infections						
Infection†	56	15‡	65	28‡	49	11
Upper respiratory tract infection§	29	1.9	26	3.4	17	2.9
Lower respiratory tract infection[a]	23	6	26	15	14	6
Blood and lymphatic system disorders[b]						
Neutropenia[c]	48	23	79	53	80	40
Anemia[d]	47	15	45	8	57	17
Thrombocytopenia[e]	33	6	41	13	54	6
Lymphocytosis[f]	26	19	23	18	2.9	2.9
Nervous system disorders						
Headache	22	0.6	6	0	0	0
Gastrointestinal disorders						
Diarrhea[g]	18	1.3	49	25	14	0
Vascular disorders						
Hemorrhage[h]	16	1.3	5	1.7	6	2.9
General disorders						
Fatigue[i]	15	1.9	13	0.8	31	6
Musculoskeletal and connective tissue disorders						
Musculoskeletal pain[j]	15	1.3	15	1.7	2.9	0

* Per NCI CTCAE version 4.03
† Includes any adverse reactions involving infection or febrile neutropenia
‡ Includes 1 fatal case in the CALQUENCE monotherapy arm and 1 fatal case in the Idelalisib plus Rituximab arm
§ Includes upper respiratory tract infection, rhinitis and nasopharyngitis
[a] Includes pneumonia, lower respiratory tract infection, bronchitis, bronchiolitis, tracheitis, and lung infection
[b] Derived from adverse reaction and laboratory data
[c] Includes neutropenia, neutrophil count decreased, and related laboratory data
[d] Includes anemia, red blood cell decreased, and related laboratory data
[e] Includes thrombocytopenia, platelet count decreased, and related laboratory data
[f] Includes lymphocytosis, lymphocyte count increased and related laboratory data
[g] Includes colitis, diarrhea, and enterocolitis
[h] Includes hemorrhage, hematoma, hemoptysis, hematuria, menorrhagia, hemarthrosis, and epistaxis
[i] Includes asthenia, fatigue, and lethargy
[j] Includes back pain, musculoskeletal chest pain, musculoskeletal pain, musculoskeletal discomfort, pain in extremity, myalgia, spinal pain and bone pain

Other clinically relevant adverse reactions (all grades incidence < 15%) in recipients of CALQUENCE included:

- *Skin and subcutaneous disorders:* bruising (10%), rash (9%)
- *Neoplasms:* second primary malignancy (12%), non-melanoma skin cancer (6%)
- *Musculoskeletal and connective tissue disorders:* arthralgia (8%)
- *Cardiac disorders:* atrial fibrillation or flutter (5%), hypertension (3.2%)
- *Infection:* herpesvirus infection (4.5%)

Table 8: Select Non-Hematologic Laboratory Abnormalities (≥ 10% Any Grade), New or Worsening from Baseline in Patients Receiving CALQUENCE (ASCEND)

Laboratory Abnormality [a]	CALQUENCE N=154		Idelalisib plus Rituximab Product N=118		Bendamustine plus Rituximab Product N=35	
	All Grades (%)	Grade ≥ 3 (%)	All Grades (%)	Grade ≥ 3 (%)	All Grades (%)	Grade ≥ 3 (%)
Uric acid increase	15	15	11	11	23	23
ALT increase	15	1.9	59	23	26	2.9
AST increase	13	0.6	48	13	31	2.9
Bilirubin increase	13	1.3	16	1.7	26	11

Per NCI CTCAE version 5
[a] Excludes electrolytes

Increases in creatinine to 1.5 to 3 times ULN occurred in 1.3% of patients who received CALQUENCE.

Postmarketing Experience

The following adverse reactions have been identified during postapproval use of CALQUENCE. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

- Cardiac disorders: ventricular arrhythmias
- Hepatobiliary disorders: drug-induced liver injury

USE IN SPECIFIC POPULATIONS

Pregnancy

Risk Summary

Based on findings in animals, CALQUENCE may cause fetal harm and dystocia when administered to a pregnant woman. There are no available data in pregnant women to inform the drug-associated risk. In animal reproduction studies, administration of acalabrutinib to animals during organogenesis resulted in dystocia in rats and reduced fetal growth in rabbits at maternal exposures (AUC) 2 times exposures in patients at the recommended dose of 100 mg approximately every 12 hours (*see Data*). Advise pregnant women of the potential risk to a fetus.

The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2 to 4% and 15 to 20%, respectively.

Data

Animal Data

In a combined fertility and embryo-fetal development study in female rats, acalabrutinib was administered orally at doses up to 200 mg/kg/day starting 14 days prior to mating through gestational day [GD] 17. No effects on embryo-fetal development and survival were observed. The AUC at 200 mg/kg/day in pregnant rats was approximately 9 times the AUC in patients at the recommended dose of 100 mg approximately every 12 hours. The presence of acalabrutinib and its active metabolite were confirmed in fetal rat plasma.

In an embryo-fetal development study in rabbits, pregnant animals were administered acalabrutinib orally at doses up to 200 mg/kg/day during the period of organogenesis (from GD 6-18). Administration of acalabrutinib at doses ≥ 100 mg/kg/day produced maternal toxicity and 100 mg/kg/day resulted in decreased fetal body weights and delayed skeletal ossification. The AUC at 100 mg/kg/day in pregnant rabbits was approximately 2 times the AUC in patients at 100 mg approximately every 12 hours.

In a pre- and postnatal development study in rats, acalabrutinib was administered orally to pregnant animals during organogenesis, parturition and lactation, at doses of 50, 100, and 150 mg/kg/day. Dystocia (prolonged or difficult labor) and mortality of offspring were observed at doses ≥ 100 mg/kg/day. The AUC at 100 mg/kg/day in pregnant rats was approximately 2 times the AUC in patients at 100 mg approximately every 12 hours. Underdeveloped renal papilla was also observed in F1 generation offspring at 150 mg/kg/day with an AUC approximately 5 times the AUC in patients at 100 mg approximately every 12 hours.

Lactation

Risk Summary

No data are available regarding the presence of acalabrutinib or its active metabolite in human milk, its effects on the breastfed child, or on milk production. Acalabrutinib and its active metabolite were present in the milk of lactating rats. Due to the potential for adverse reactions in a breastfed child from CALQUENCE, advise lactating women not to breastfeed while taking CALQUENCE and for 2 weeks after the last dose.

Females and Males of Reproductive Potential

CALQUENCE may cause embryo-fetal harm and dystocia when administered to pregnant women *[see Use in Specific Populations (8.1) in the full Prescribing Information]*.

Pregnancy Testing

Pregnancy testing is recommended for females of reproductive potential prior to initiating CALQUENCE therapy.

Contraception

Females

Advise female patients of reproductive potential to use effective contraception during treatment with CALQUENCE and for 1 week following the last dose of CALQUENCE. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be informed of the potential hazard to a fetus.

Pediatric Use

The safety and efficacy of CALQUENCE in pediatric patients have not been established.

Geriatric Use

Of the 929 patients in clinical trials of CALQUENCE, 68% were 65 years of age or older, and 24% were 75 years of age or older. Among patients 65 years of age or older, 59% had Grade 3 or higher adverse reactions and 39% had serious adverse reactions. Among patients younger than age 65, 45% had Grade 3 or higher adverse reactions and 25% had serious adverse reactions. No clinically relevant differences in efficacy were observed between patients ≥ 65 years and younger.

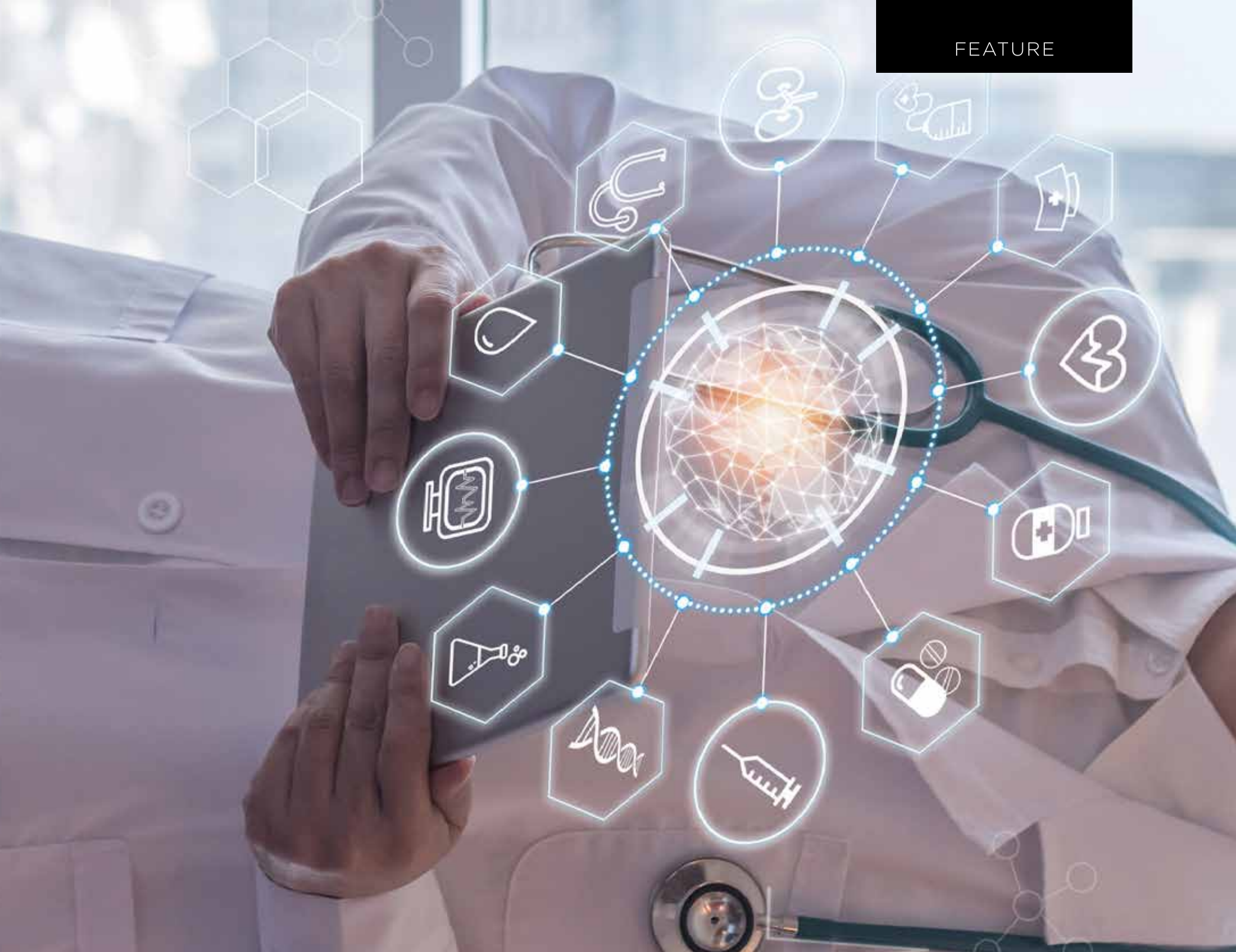
Hepatic Impairment

Avoid use of CALQUENCE in patients with severe hepatic impairment (Child-Pugh class C). No dosage adjustment of CALQUENCE is recommended in patients with mild (Child-Pugh class A) or moderate (Child-Pugh class B) hepatic impairment. The safety of CALQUENCE has not been evaluated in patients with moderate or severe hepatic impairment *[see Clinical Pharmacology (12.3) in the full Prescribing Information]*.

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06/24 US-91538 7/24



AI Medical Scribes

BY: MICHAEL BAKER
STAFF WRITER PHYSICIANS OFFICE RESOURCE

When a physician sees 10-25 patients per day those visits can easily blend together by the end of the day. Keeping them straight is vital to the patient's treatment, safety, and to the physician's sanity. Documenting visits has long been part of the game with physicians, whether it's been a medical scribe that silently sits in the corner documenting the entire patient visit on their laptop. Or a physician pausing during the examination to take notes on their own device or voice recorder. It's something that must be done and done correctly.

In the new age of artificial intelligence (AI), AI-powered medical scribes have quickly emerged as transformative tools for the healthcare industry. With advancements in natural language processing (NLP) and machine learning, these systems now offer capabilities that were previously unimaginable. Designed to streamline documentation, AI scribes assist in creating electronic health records (EHR) entries by capturing patient-provider interactions in real-time. For physicians, this innovation promises time savings, reduced administrative load, and potentially improved patient care. However, it also introduces challenges and ethical considerations, prompting physicians to carefully evaluate whether AI medical scribes align with their practice's needs.

In this article, we'll examine AI medical scribes, their advantages and drawbacks, and practical tips to help physicians decide if this technology is a good fit for their practice.

Understanding AI Medical Scribes

An AI medical scribe is a digital assistant equipped with NLP algorithms to interpret, document, and structure patient interactions. These AI tools "listen" during patient visits, either through audio capture or EHR integration, and produce structured notes that a physician can review and approve. Unlike traditional human scribes, AI medical scribes offer speed, scalability, and can work around the clock without fatigue, making them attractive to practices seeking efficiency.

Benefits of AI Medical Scribes for Physicians

Enhanced Time Efficiency: One of the most widely acknowledged advantages of AI scribes is their ability to free physicians from the extensive time demands of documentation. Studies have shown that EHR tasks can consume up to half of a physician's workday. AI scribes reduce the time spent manually inputting notes, offering immediate transcriptions that physicians can review, edit, and approve, freeing them up for patient care.

Improved Workflow and Productivity: AI scribes can integrate directly with EHR systems, enabling seamless information transfer. This real-time documentation helps streamline the process, allowing healthcare providers to work more efficiently and avoid end-of-day backlog, which has historically led to increased after-hours work and physician burnout.

Reduced Physician Burnout: Administrative burden is a major contributor to physician burnout. By lightening this load, AI medical scribes can help reduce stress and support physician well-being. This also benefits patient care, as physicians with lighter administrative demands can spend more time focusing on clinical matters and building patient relationships.

Enhanced Patient-Physician Interaction: When physicians aren't focused on screens and typing, they can dedicate more attention to their patients. With AI handling the documentation, patient encounters can feel more personal and engaging, potentially improving patient satisfaction and quality of care.

Consistency and Scalability: AI scribes are not prone to the scheduling and availability issues associated with human scribes. Practices with fluctuating patient volumes may benefit from the consistency and scalability of AI technology, especially in settings where hiring and training new staff might be a challenge.

Challenges and Limitations of AI Medical Scribes

Accuracy and Reliability Concerns: While AI medical scribes have made significant strides, the risk of inaccuracies remains.

AI algorithms may misinterpret medical jargon, patient accents, or soft-spoken individuals, leading to potential documentation errors. Additionally, these systems often require physician oversight to ensure all notes are complete and correctly reflect the patient's visit.

Over-Reliance on Technology: Physicians may find it tempting to trust AI documentation fully, which could reduce vigilance in reviewing notes for accuracy. An over-reliance on AI could lead to errors if physicians assume the technology always records patient information correctly, potentially impacting patient safety.

Data Security and Privacy: AI medical scribes handle sensitive patient information, creating potential risks if data is not managed securely. Compliance with HIPAA and other data privacy laws is essential, yet challenging, as these systems rely on cloud-based storage, data transmission, and real-time processing. Ensuring that the AI scribe provider has strong security measures and HIPAA compliance is essential to protect patient data.

Implementation and Cost: While AI scribes can lead to long-term savings, initial implementation can be costly. From software setup and integration with EHR systems to training and ongoing support, the upfront investment might be significant. Smaller practices may find this financial commitment challenging without clear evidence of return on investment.

Limited Adaptability and Contextual Understanding: Although AI scribes can capture standard patient interactions, they may struggle with complex cases or situations requiring nuanced understanding. For example, conversations involving complex diagnostic reasoning or subtle patient cues might not be fully captured, potentially impacting the quality of documentation.

Practical Considerations for Implementing an AI Medical Scribe

If you are considering an AI medical scribe, here are practical steps and considerations to guide your decision-making process:

Evaluate Practice Needs: Assess whether documentation tasks are consuming substantial time and impacting patient care. If your practice handles high volumes or complex documentation, AI scribes may provide the efficiency boost you need.

Research Vendor Offerings: With many AI scribe solutions on the market, conduct thorough research on vendors to find a system that aligns with your practice's specific needs. Compare features, reliability, and customer support to ensure you select a reputable provider.

Assess Data Security and Compliance: Confirm that the AI scribe complies with HIPAA and other privacy standards. Review the provider's data security measures, including encryption and secure data storage, to protect sensitive patient information.

Trial Period and Staff Feedback: Consider running a trial period to see how well the AI scribe integrates with your practice's workflow. Engage your team in providing feedback to gauge the system's performance and user-friendliness. Training staff to use the AI scribe effectively is crucial to successful implementation.

Continued Human Oversight: Even with an AI scribe, human oversight remains essential. Regularly review and verify notes to maintain high accuracy levels. Establish guidelines for checking documentation and correcting any errors to ensure patient records are complete and accurate.

Cost-Benefit Analysis: Calculate the potential return on investment by evaluating how much time and administrative work AI scribes can save. Consider whether the anticipated efficiency gains outweigh the initial and ongoing costs of implementation.

Future Directions and Potential for Growth

AI medical scribes represent just the beginning of a broader transformation in healthcare documentation. As NLP and machine learning technologies continue to advance, future iterations may offer even greater accuracy, adaptability, and functionality. For example, upcoming AI models may be able to provide diagnostic support or flag potential red flags in patient data, further enhancing clinical decision-making.

AI scribes could also expand into other areas, such as patient intake, billing documentation, and medical coding. However, as the technology grows more sophisticated, regulatory and ethical considerations will be increasingly important to ensure AI systems are used responsibly and with patient safety as the priority.

Is an AI Medical Scribe Right for Your Practice?

AI medical scribes have significant potential to reduce administrative burdens, increase efficiency, and improve patient care. However, they also bring challenges, including accuracy concerns, data privacy issues, and financial costs. For a physician or practice considering this technology, it's essential to weigh the benefits against potential risks and to approach implementation thoughtfully.

Ultimately, an AI scribe may be a valuable addition to a practice focused on improving efficiency and patient interaction, provided there is commitment to maintaining human oversight and upholding data security standards. By carefully evaluating your practice's unique needs and integrating AI with a balanced approach, you can harness this technology to enhance healthcare delivery while safeguarding patient care quality.

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1. Smolderen KG, Ameli O, Chaisson CE, Heath K, Mena-Hurtado C. Peripheral Artery Disease Screening in the Community and 1-Year Mortality, Cardiovascular Events, and Adverse Limb Events, AJPM Focus (2022), https://doi.org/10.1016/j.focus.2022.100016

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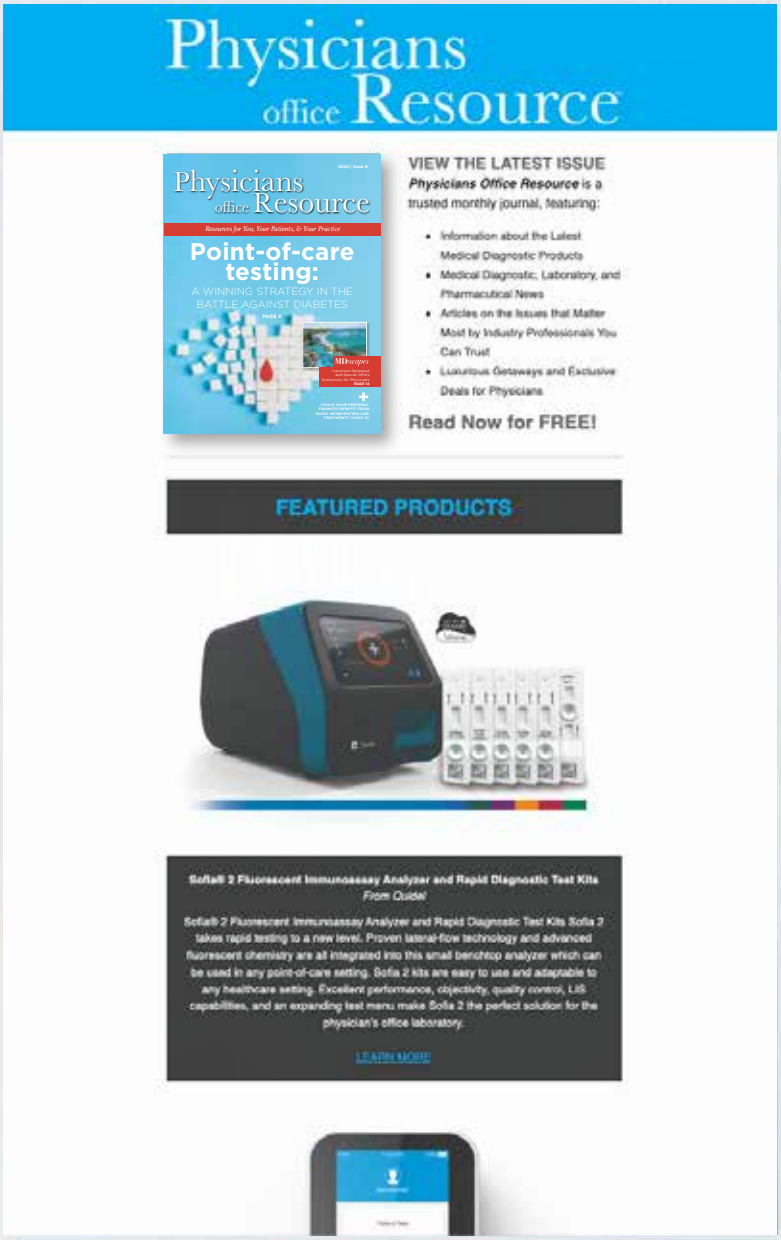
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REIGNITE THE SPARK

Jaypirca®
pirtobrutinib 50, 100 mg tablets



Jaypirca is the **first-and-only** approved reversible (noncovalent) BTK inhibitor that can reestablish response to help move adult patients with CLL/SLL forward after ≥2 prior lines, including a BTKi and BCL2i[1,2]

Indication

Jaypirca is a kinase inhibitor indicated for the treatment of adult patients with chronic lymphocytic leukemia or small lymphocytic lymphoma (CLL/SLL) who have received at least two prior lines of therapy, including a BTK inhibitor and a BCL-2 inhibitor.

This indication is approved under accelerated approval based on response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

Important Safety Information for Jaypirca (pirtobrutinib)

Infections: Fatal and serious infections (including bacterial, viral, fungal) and opportunistic infections occurred in Jaypirca-treated patients. In a clinical trial, Grade ≥3 infections occurred in 24% of patients with hematologic malignancies, most commonly pneumonia (14%); fatal infections occurred (4.4%). Sepsis (6%) and febrile neutropenia (4%) occurred. In patients with CLL/SLL, Grade ≥3 infections occurred (32%), with fatal infections occurring in 8%. Opportunistic infections included *Pneumocystis jirovecii* pneumonia and fungal infection. Consider prophylaxis, including vaccinations and antimicrobial prophylaxis, in patients at increased risk for infection, including opportunistic infections. Monitor patients for signs and symptoms, evaluate promptly, and treat appropriately. Based on severity, reduce dose, temporarily withhold, or permanently discontinue Jaypirca.

Hemorrhage: Fatal and serious hemorrhage has occurred with Jaypirca. Major hemorrhage (Grade ≥3 bleeding or any central nervous system bleeding) occurred in 3% of patients, including gastrointestinal hemorrhage; fatal hemorrhage occurred (0.3%). Bleeding of any grade, excluding bruising and petechiae, occurred (17%). Major hemorrhage occurred in patients taking Jaypirca with (0.7%) and without (2.3%) antithrombotic agents. Consider risks/benefits of co-administering antithrombotic agents with Jaypirca. Monitor patients for signs of bleeding. Based on severity, reduce dose, temporarily withhold, or permanently discontinue Jaypirca. Consider benefit/risk of withholding Jaypirca 3-7 days pre- and post-surgery depending on type of surgery and bleeding risk.

Cytopenias: Jaypirca can cause cytopenias, including neutropenia, thrombocytopenia, and anemia. In a clinical trial, Grade 3 or 4 cytopenias, including decreased neutrophils (26%), decreased platelets (12%), and decreased hemoglobin (12%), developed in Jaypirca-treated patients. Grade 4 decreased neutrophils (14%) and Grade 4 decreased platelets (6%) developed. Monitor complete blood counts regularly during treatment. Based on severity, reduce dose, temporarily withhold, or permanently discontinue Jaypirca.

Cardiac Arrhythmias: Cardiac arrhythmias occurred in patients who received Jaypirca. In a clinical trial of patients with hematologic malignancies, atrial fibrillation or flutter were reported in 3.2% of Jaypirca-treated patients, with Grade 3 or 4 atrial fibrillation or flutter in 1.5%. Other serious cardiac arrhythmias such as supraventricular tachycardia and cardiac arrest occurred (0.5%). Patients with cardiac risk factors such as hypertension or previous arrhythmias may be at increased risk. Monitor for signs and symptoms of arrhythmias (e.g., palpitations, dizziness, syncope, dyspnea) and manage appropriately. Based on severity, reduce dose, temporarily withhold, or permanently discontinue Jaypirca.

Second Primary Malignancies: Second primary malignancies, including non-skin carcinomas, developed in 9% of Jaypirca-treated patients. The most frequent malignancy was non-melanoma skin cancer (4.6%). Other second primary malignancies included solid tumors (including genitourinary and breast cancers) and melanoma. Advise patients to use sun protection and monitor for development of second primary malignancies.

Hepatotoxicity, Including Drug-Induced Liver Injury (DILI): Hepatotoxicity, including severe, life-threatening, and potentially fatal cases of DILI, has occurred in patients treated with BTK inhibitors, including Jaypirca. Evaluate bilirubin and transaminases at baseline and throughout Jaypirca treatment. For patients who develop abnormal liver tests after Jaypirca, monitor more frequently for liver test abnormalities and clinical signs and symptoms of hepatic toxicity. If DILI is suspected, withhold Jaypirca. Upon confirmation of DILI, discontinue Jaypirca.

Embryo-Fetal Toxicity: Jaypirca can cause fetal harm in pregnant women. Administration of pirtobrutinib to pregnant rats caused embryo-fetal toxicity, including embryo-fetal mortality and malformations at maternal exposures (AUC) approximately 3-times the recommended 200 mg/day dose. Advise pregnant women of potential fetal risk and females of reproductive potential to use effective contraception during treatment and for one week after last dose.

Adverse Reactions (ARs) in Patients with Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma

Serious ARs occurred in 56% of patients. Serious ARs occurring in ≥5% of patients were pneumonia (18%), COVID-19 (9%), sepsis (7%), and febrile neutropenia (7%). **Fatal ARs** within 28 days of last Jaypirca dose occurred in 11% of patients, most commonly due to infections (10%), including sepsis (5%) and COVID-19 (2.7%).

Dose Modifications and Discontinuations: ARs led to dose reductions in 3.6%, treatment interruption in 42%, and permanent discontinuation of Jaypirca in 9% of patients. ARs resulting in dose reductions in >1% of patients included neutropenia; treatment interruptions in >5% of patients included pneumonia, neutropenia, febrile neutropenia, and COVID-19; permanent discontinuation in >1% of patients included second primary malignancy, COVID-19, and sepsis.

Please see Important Safety Information and Brief Summary of Prescribing Information for Jaypirca on subsequent pages.

In adults with CLL/SLL after ≥2 prior lines, including a BTKi and BCL2i (n=108)

Jaypirca delivered a **robust response**[1]

ORR with 200 mg daily (n=108)[1]*



Median DoR[1†‡§]



12.2 **months - Median DoR** in patients who responded (95% CI: 9.3, 14.7) (n=78)

- The estimated median follow-up was 15.7 months[††]

BRUIN Study Design

The phase 1/2, open-label, multicohort, single-arm BRUIN trial evaluated Jaypirca as monotherapy in 593 adult patients with hematologic malignancies, including adults with CLL/SLL previously treated with a BTKi and BCL2i who received Jaypirca 200 mg orally once daily until disease progression or unacceptable toxicity. The trial required patients with a platelet count ≥50 x 10^9/L, absolute neutrophil count ≥0.75 x 10^9/L, hepatic transaminases ≤2.5 times ULN, and an ECOG performance of 0 to 2. The safety (n=110)[‡] of Jaypirca was evaluated in adults with CLL/SLL previously treated with a BTKi[¶] and BCL2i, who had received a median of 5 prior lines of therapy (range: 1-11). The efficacy (n=108)[‡] of Jaypirca was evaluated in adults with CLL/SLL after two or more prior lines of therapy, including a BTKi[¶] and BCL2i, who had received a median of 5 prior lines of therapy (range: 2-11). The phase 2 primary endpoint was overall response rate (ORR).** Efficacy of Jaypirca was based on response as assessed by an IRC using 2018 iwCLL criteria.[1,2]

*ORR, the primary endpoint, includes patients with a best response of PR or better and was assessed by IRC using 2018 iwCLL criteria.[1]

†Based on Kaplan-Meier estimation.[1]

‡DoR was calculated for patients who achieved a response of PR or better and was defined as the time from first evidence of response to progression or death from any cause.[1]

§The primary endpoint was ORR. Efficacy was based on 108 patients with CLL/SLL who were previously treated with ≥2 prior lines of therapy, including a BTK inhibitor and a BCL-2 inhibitor.[1,2]

‖Trial excluded patients with active CNS involvement by lymphoma, allogeneic HSCT within 60 days, significant cardiovascular disease, major bleeding, uncontrolled or symptomatic arrhythmias, prolonged QTc interval, or need for strong CYP3A inhibitor or inducer or strong P-gp inhibitor.[1]

¶Ibrutinib (97%), acalabrutinib (9%), and zanubrutinib (0.9%) in the efficacy population.[1]

**The phase 1 primary outcome was to determine maximum tolerated dose and recommended phase 2 dose. All patients received at least one dose of Jaypirca.[2]

BCL-2=B-cell lymphoma 2; BCL2i=B-cell lymphoma 2 inhibitor; BTK=Bruton's tyrosine kinase; BTKi=Bruton's tyrosine kinase inhibitor; CI=confidence interval; CNS=central nervous system; CR=complete response; DoR=duration of response; ECOG=Eastern Cooperative Oncology Group; HSCT=hematopoietic stem cell transplantation; IRC=independent review committee; iwCLL=International Workshop on Chronic Lymphocytic Leukemia; ORR=overall response rate; PR=partial response; ULN=upper limit of normal.

Important Safety Information (cont'd)

Most common ARs (≥20%), excluding laboratory terms (all Grades %; Grade 3-4 %): fatigue (36; 2.7), bruising (36; -), cough (33; -), musculoskeletal pain (32; 0.9), COVID-19 (28; 7), pneumonia (27; 16), diarrhea (26; -), abdominal pain (25; 2.7), dyspnea (22; 2.7), hemorrhage (22; 2.7), edema (21; -), nausea (21; -), pyrexia (20; 2.7), headache (20; 0.9).

Select Laboratory Abnormalities (all Grades %; Grade 3 or 4 %) that Worsened from Baseline in ≥20% of Patients: neutrophil count decreased (63; 45), hemoglobin decreased (48; 19), calcium decreased (40; 2.8), platelet count decreased (30; 15), sodium decreased (30; -), lymphocyte count decreased (23; 8), ALT increased (23; 2.8), AST increased (23; 1.9), creatinine increased (23; -), lipase increased (21; 7), alkaline phosphatase increased (21; -). Grade 4 laboratory abnormalities in >5% of patients included neutrophils decreased (23).

The most common (≥20%) ARs in the BRUIN pooled safety population of patients with hematologic malignancies (n=593) were decreased neutrophil count (46%), decreased hemoglobin (39%), fatigue (32%), decreased lymphocyte count (31%), musculoskeletal pain (30%), decreased platelet count (29%), diarrhea (24%), COVID-19 (22%), bruising (21%), cough (20%).

Drug Interactions

Strong CYP3A Inhibitors: Concomitant use with Jaypirca increased pirtobrutinib systemic exposure, which may increase risk of Jaypirca ARs. Avoid use of strong CYP3A inhibitors with Jaypirca. If concomitant use is unavoidable, reduce Jaypirca dosage according to approved labeling.

Strong or Moderate CYP3A Inducers: Concomitant use with Jaypirca decreased pirtobrutinib systemic exposure, which may reduce Jaypirca efficacy. Avoid concomitant use of Jaypirca with strong or moderate CYP3A inducers. If concomitant use with moderate CYP3A inducers is unavoidable, increase Jaypirca dosage according to approved labeling.

Sensitive CYP2C8, CYP2C19, CYP3A, P-gp, or BCRP Substrates: Concomitant use with Jaypirca increased their plasma concentrations, which may increase risk of adverse reactions related to these substrates for drugs that are sensitive to minimal concentration changes. Follow recommendations for these sensitive substrates in their approved labeling.

Use in Special Populations

Pregnancy and Lactation: Due to potential for Jaypirca to cause fetal harm, verify pregnancy status in females of reproductive potential prior to starting Jaypirca and advise use of effective contraception during treatment and for one week after last dose. Presence of pirtobrutinib in human milk is unknown. Advise women not to breastfeed while taking Jaypirca and for one week after last dose.

Geriatric Use: In the pooled safety population of patients with hematologic malignancies, patients aged ≥65 years experienced higher rates of Grade ≥3 ARs and serious ARs compared to patients <65 years of age.

Renal Impairment: Severe renal impairment increases pirtobrutinib exposure. Reduce Jaypirca dosage in patients with severe renal impairment according to approved labeling.

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Please see Important Safety Information on previous page and Brief Summary of Prescribing Information for Jaypirca on subsequent pages.

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References: **1.** Jaypirca. Prescribing Information. Lilly USA, LLC. **2.** Mato AR, Shah NN, Jurczak W, et al. Pirtobrutinib in relapsed or refractory B-cell malignancies (BRUIN): a phase 1/2 study. Lancet. 2021;397(10277):892-901. **3.** Mato AR, Shah NN, Jurczak W, et al. Pirtobrutinib in relapsed or refractory B-cell malignancies (BRUIN): a phase 1/2 study. Lancet. 2021;397(10277)(suppl app):1-158.

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Jaypirca® pirtobrutinib 50, 100 mg tablets

Lilly

Jaypirca® (pirtobrutinib) tablets, for oral use
Initial U.S. Approval: 2023

Brief Summary: Consult the package insert for complete prescribing information.

INDICATIONS AND USAGE

Jaypirca is indicated for the treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL) after at least two lines of systemic therapy, including a BTK inhibitor. This indication is approved under accelerated approval based on response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

Jaypirca is indicated for the treatment of adult patients with chronic lymphocytic leukemia or small lymphocytic lymphoma (CLL/SLL) who have received at least two prior lines of therapy, including a BTK inhibitor and a BCL-2 inhibitor. This indication is approved under accelerated approval based on response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

CONTRAINDICATIONS: None

WARNINGS AND PRECAUTIONS

Infections: Fatal and serious infections (including bacterial, viral, or fungal infections) and opportunistic infections have occurred in patients treated with Jaypirca. In the clinical trial, Grade 3 or higher infections occurred in 24% of 593 patients, most commonly pneumonia (14%), with fatal infections occurring in 4.4% of patients. Sepsis occurred in 6% of patients and febrile neutropenia in 4%. In patients with CLL/SLL, Grade 3 or higher infections occurred in 32% of patients, with fatal infections occurring in 8%. Opportunistic infections after treatment with Jaypirca have included, but are not limited to, *Pneumocystis jirovecii* pneumonia and fungal infection *[*see *Adverse Reactions]*.

Consider prophylaxis, including vaccinations and antimicrobial prophylaxis, in patients who are at increased risk for infections, including opportunistic infections. Monitor patients for signs and symptoms of infection, evaluate promptly, and treat appropriately. Based on severity, reduce dose, temporarily withhold, or permanently discontinue Jaypirca *[*see *Dosage and Administration]*.

Hemorrhage: Fatal and serious hemorrhage has occurred with Jaypirca. Major hemorrhage (defined as Grade 3 or higher bleeding or any central nervous system bleeding) occurred in 3% of 593 patients treated with Jaypirca, including gastrointestinal hemorrhage; fatal hemorrhage occurred in 0.3% of patients. Bleeding of any grade, excluding bruising and petechiae, occurred in 17% of patients.

Major hemorrhage occurred in 2.3% of patients taking Jaypirca without antithrombotic agents and 0.7% of patients taking Jaypirca with antithrombotic agents. Consider the risks and benefits of antithrombotic agents when co-administered with Jaypirca. Monitor patients for signs of bleeding. Based on severity of bleeding, reduce dose, temporarily withhold, or permanently discontinue Jaypirca *[*see *Dosage and Administration]*.

Consider the benefit-risk of withholding Jaypirca for 3 to 7 days pre- and post-surgery depending upon the type of surgery and risk of bleeding.

Cytopenias: Jaypirca can cause cytopenias, including neutropenia, thrombocytopenia, and anemia. In the clinical trial, Grade 3 or 4 cytopenias, including decreased neutrophils (26%), decreased platelets (12%), and decreased hemoglobin (12%), developed in patients treated with Jaypirca. Grade 4 decreased neutrophils developed in 14% of patients and Grade 4 decreased platelets developed in 6% of patients *[*see *Adverse Reactions]*.

Monitor complete blood counts regularly during treatment. Based on severity, reduce dose, temporarily withhold, or permanently discontinue Jaypirca *[*see *Dosage and Administration]*.

Cardiac Arrhythmias: Cardiac arrhythmias, including atrial fibrillation and atrial flutter, were reported in recipients of JAYPIRCA. Atrial fibrillation or flutter were reported in 3.2% of patients, with Grade 3 or 4 atrial fibrillation or flutter reported in 1.5% of 593 patients in the clinical trial *[*see *Adverse Reactions]*. Other serious cardiac arrhythmias such as supraventricular tachycardia and cardiac arrest occurred in 0.5% of patients. Patients with cardiac risk factors, such as hypertension or previous arrhythmias may be at increased risk.

Monitor for signs and symptoms of arrhythmias (e.g., palpitations, dizziness, syncope, dyspnea) and manage appropriately. Based on severity, reduce dose, temporarily withhold, or permanently discontinue Jaypirca *[*see *Dosage and Administration]*.

Second Primary Malignancies: Second primary malignancies, including non-skin carcinomas, developed in 9% of 593 patients treated with Jaypirca monotherapy. The most frequent malignancy was non-melanoma skin cancer, reported in 4.6% of 593 patients. Other second primary malignancies included solid tumors (including genitourinary and breast cancers) and melanoma. Advise patients to use sun protection and monitor patients for the development of second primary malignancies.

Hepatotoxicity, Including Drug-Induced Liver Injury: Hepatotoxicity, including severe, life-threatening, and potentially fatal cases of drug-induced liver injury (DILI), has occurred in patients treated with Bruton tyrosine kinase inhibitors, including Jaypirca. Evaluate bilirubin and transaminases at baseline and throughout treatment with Jaypirca. For patients who develop abnormal liver tests after Jaypirca, monitor more frequently for liver test abnormalities and clinical signs and symptoms of hepatic toxicity. If DILI is suspected, withhold Jaypirca. Upon confirmation of DILI, discontinue Jaypirca.

Embryo-Fetal Toxicity: Based on findings in animals, Jaypirca can cause fetal harm when administered to a pregnant woman. In animal reproduction studies, administration of pirtobrutinib to pregnant rats during the period of organogenesis caused embryo-fetal toxicity including embryo-fetal mortality and malformations at maternal exposures (AUC) approximately 3-times the recommended dose of 200 mg once daily. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with Jaypirca and for one week after the last dose *[*see *use in Specific Populations]*.

ADVERSE REACTIONS

The following clinically significant adverse reactions are described elsewhere in the labeling *[*see *Warnings and Precautions]*:
Infections, Hemorrhage, Cytopenias, Atrial Fibrillation and Atrial Flutter, Second Primary Malignancies, and Hepatotoxicity, including DILI.

Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be compared to rates in the clinical trials of another drug and may not reflect the rates observed in the general patient population.

The data in the WARNINGS AND PRECAUTIONS reflect exposure to Jaypirca as a single-agent, administered at 200 mg once daily in 593 patients with hematologic malignancies in the BRUIN study. Among these 593 patients, the median duration of exposure was 10 months, 62% were exposed for at least 6 months and 45% were exposed for at least one year.

In this pooled safety population, the most common (≥ 20%) adverse reactions, including laboratory abnormalities, were decreased neutrophil count (46%), decreased hemoglobin (39%), fatigue (32%), decreased lymphocyte count (31%), musculoskeletal pain (30%), decreased platelet count (29%), diarrhea (24%), COVID-19 (22%), bruising (21%), and cough (20%).

Mantle Cell Lymphoma

BRUIN: The safety of Jaypirca was evaluated in the BRUIN trial in patients with MCL who received a prior BTK inhibitor. The trial required a platelet count ≥ 50 x 10^9/L, absolute neutrophil count ≥ 0.75 x 10^9/L, hepatic transaminases ≤ 2.5 times upper limit of normal (ULN), and an ECOG performance status of 0 to 2. The trial excluded patients with active central nervous system (CNS) involvement by lymphoma, significant cardiovascular disease, major bleeding or grade ≥ 3 arrhythmia with a prior BTK inhibitor, prolonged QTc interval, or need for a strong CYP3A inhibitor or inducer or strong P-gp inhibitor.

Patients received Jaypirca 200 mg orally once daily until disease progression or unacceptable toxicity (n = 128); 36% were exposed for 6 months or longer and 10% were exposed for at least one year. The median number of prior therapies was 3 (range: 1-9). The median age was 71 years (range: 46 to 88 years) and 80% of patients were male. Race was reported for all patients; 78% were White, 14% were Asian, 2.3% were Black, and 2.3% were Hispanic or Latino.

Serious adverse reactions occurred in 38% of patients who received Jaypirca. Serious adverse reactions that occurred in ≥ 2% of patients were pneumonia (14%), COVID-19 (4.7%), musculoskeletal pain (3.9%), hemorrhage (2.3%), pleural effusion (2.3%), and sepsis (2.3%). Fatal adverse reactions within 28 days of the last dose of Jaypirca occurred in 7% of patients, most commonly due to infections (4.7%) including COVID-19 (3.1% of all patients).

Adverse reactions led to dose reductions in 4.7%, treatment interruption in 32%, and permanent discontinuation of Jaypirca in 9%. Adverse reactions that resulted in dosage modification in > 5% of patients included pneumonia and neutropenia. Adverse reactions which resulted in permanent discontinuation of Jaypirca in > 1% of patients included pneumonia.

The most common adverse reactions (≥ 15%), excluding laboratory terms, were fatigue, musculoskeletal pain, diarrhea, edema, dyspnea, pneumonia, and bruising.

Table 1 summarizes select adverse reactions in BRUIN.

Table 1: Adverse Reactions (≥ 10%) in Patients with MCL Who Received Jaypirca

	Jaypirca 200 mg once daily	
	N=128	
Adverse Reactions[a]	**All Grades (%)**	**Grade 3-4 (%)**
General Disorders		
Fatigue	29	1.6
Edema	18	0.8
Fever	13	-
Musculoskeletal and Connective Tissue Disorders		
Musculoskeletal pain	27	3.9
Arthritis or arthralgia	12	0.8
Gastrointestinal Disorders		
Diarrhea	19	-
Constipation	13	-
Abdominal pain	11	0.8
Nausea	11	-

Jaypirca® (pirtobrutinib) tablets, for oral use PT HCP BS JUN2024

Table 1: Adverse Reactions (≥ 10%) in Patients with MCL Who Received Jaypirca (Cont.)

	Jaypirca 200 mg once daily	
	N=128	
Adverse Reactions[a]	**All Grades (%)**	**Grade 3-4 (%)**
Respiratory, thoracic, and mediastinal disorders		
Dyspnea	17	2.3
Cough	14	-
Injury		
Bruising	16	-
Infections		
Pneumonia	16[b]	14
Upper respiratory tract infections	10	0.8
Nervous system disorders		
Peripheral neuropathy	14	0.8
Dizziness	10	-
Skin and subcutaneous disorders		
Rash	14	-
Vascular disorders		
Hemorrhage	11[c]	3.1

[a]Each term listed includes other related terms
[b]includes 1 fatality from COVID-19 pneumonia
[c]includes 1 fatality from hemorrhage

Clinically relevant adverse reactions in < 10% include vision changes, memory changes, headache, urinary tract infection, herpesvirus infection, and tumor lysis syndrome.

Table 2 summarizes laboratory abnormalities in BRUIN.

Table 2: Select Laboratory Abnormalities (≥ 10%) That Worsened from Baseline in Patients with MCL Who Received Jaypirca

Laboratory Abnormality	Jaypirca[a] 200 mg once daily	
	All Grades (%)	**Grade 3 or 4 (%)**
Hematology		
Hemoglobin decreased	42	9
Platelet count decreased	39	14
Neutrophil count decreased	36	16
Lymphocyte count decreased	32	15
Chemistry		
Creatinine increased	30	1.6
Calcium decreased	19	1.6
AST increased	17	1.6
Potassium decreased	13	1.6
Sodium decreased	13	-
Lipase increased	12	4.4
Alkaline phosphatase increased	11	-
ALT increased	11	1.6
Potassium increased	11	0.8

[a] The denominator used to calculate the rate varied from 90 to 127 based on the number of patients with a baseline value and at least one post-treatment value.

Grade 4 laboratory abnormalities in > 5% of patients included neutrophils decreased (10%), platelets decreased (7%), and lymphocytes decreased (6%).

Lymphocytosis: Upon initiation of Jaypirca, a temporary increase in lymphocyte counts (defined as absolute lymphocyte count increased ≥ 50% from baseline and a post-baseline value ≥ 5,000/µL) occurred in 34% of MCL patients in BRUIN. The median time to onset of lymphocytosis was 1.1 weeks, with 75% of cases occurring within 2.1 weeks, and the median duration was 11 weeks.

Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma

BRUIN: The safety of Jaypirca was evaluated in the BRUIN trial in 110 patients with CLL/SLL, with 98% receiving at least two prior lines of systemic therapy including a BTK inhibitor and a BCL-2 inhibitor. The trial required a platelet count ≥ 50 x 10^9/L, absolute neutrophil count ≥ 0.75 x 10^9/L, hepatic transaminases ≤ 2.5 times upper limit of normal (ULN), and an ECOG performance status of 0 to 2. The trial excluded patients with active central nervous system (CNS) involvement by lymphoma, significant cardiovascular disease, major bleeding, uncontrolled or symptomatic arrhythmias, prolonged QTc interval, or need for a strong CYP3A inhibitor or inducer or strong P-gp inhibitor.

Patients received Jaypirca 200 mg orally once daily until disease progression or unacceptable toxicity (N = 110); 60% were exposed for at least 1 year and 14% were exposed for at least two years. The median age was 68 years (range: 41 to 88 years) and 67% of patients were male. Race was reported in 110 (100%) patients; of these patients, 89% were White, 4.5% were Black, 1.8% were Asian, and 1.8% were Hispanic or Latino. The median number of prior therapies was 5 (range: 1-11).

Serious adverse reactions occurred in 56% of patients who received Jaypirca. Serious adverse reactions that occurred in ≥ 5% of patients were pneumonia (18%), COVID-19 (9%), sepsis (7%), and febrile neutropenia (7%). Fatal adverse reactions within 28 days of the last dose of Jaypirca occurred in 11% of patients, most commonly due to infections (10%), including sepsis (5%) and COVID-19 (2.7%).

Adverse reactions led to dose reductions in 3.6%, treatment interruption in 42%, and permanent discontinuation of Jaypirca in 9%. Adverse reactions which resulted in dose reductions of Jaypirca in > 1% of patients included neutropenia. Adverse reactions which resulted in treatment interruptions of Jaypirca in >5% of patients included pneumonia, neutropenia, febrile neutropenia, and COVID-19. Adverse reactions which resulted in permanent discontinuation of Jaypirca in > 1% of patients included second primary malignancy, COVID-19, and sepsis.

The most common adverse reactions (≥ 20%), excluding laboratory terms, were fatigue, bruising, cough, musculoskeletal pain, COVID-19, diarrhea, pneumonia, abdominal pain, dyspnea, hemorrhage, edema, nausea, pyrexia, and headache.

Table 3 summarizes select adverse reactions for patients treated in BRUIN.

Table 3: Adverse Reactions (≥ 10%) in Patients with CLL/SLL Who Received Jaypirca

	Jaypirca 200 mg once daily	
	N=110	
Adverse Reactions[a]	**All Grades (%)**	**Grade 3-4 (%)**
General Disorders		
Fatigue	36	2.7
Edema	21	0
Pyrexia	20	2.7
Injury		
Bruising	36	0
Fall	14	0.9
Respiratory, thoracic, and mediastinal disorders		
Cough	33	0
Dyspnea	22	2.7
Mucositis	12	0.9
Musculoskeletal and Connective Tissue Disorders		
Musculoskeletal pain	32	0.9
Arthritis or arthalgia	19	1.8
Infections		
COVID-19	28[b]	7
Pneumonia	27[c]	16
Upper respiratory tract infections	13	2.7
Respiratory tract infection	11	1.8
Gastrointestinal Disorders		
Diarrhea	26	0
Abdominal pain	25	2.7
Nausea	21	0
Constipation	14	0
Vascular disorders		
Hemorrhage	22[d]	2.7
Hypertension	12	5
Nervous system disorders		
Headache	20	0.9
Peripheral neuropathy	16	3.6
Dizziness	15	0
Neurological changes	12[e]	2.7
Skin and subcutaneous disorders		
Rash	19	0.9
Psychiatric disorders		
Insomnia	14	0

Jaypirca® (pirtobrutinib) tablets, for oral use PT HCP BS JUN2024

Table 3: Adverse Reactions (≥ 10%) in Patients with CLL/SLL Who Received Jaypirca (Cont.)

	Jaypirca 200 mg once daily	
	N=110	
Adverse Reactions[a]	**All Grades (%)**	**Grade 3-4 (%)**
Neoplasms benign, malignant and unspecified		
Second primary malignancy	13[f]	2.7
Renal and urinary disorders		
Renal insufficiency	12[g]	6
Metabolism and nutrition disorders		
Decreased appetite	12	0
Cardiac disorders		
Supraventricular tachycardia	10[h]	5

[a] Each term listed includes other related terms.
[b] Includes COVID-19 pneumonia. Includes 1 fatality from COVID-19 and 2 fatalities from COVID-19 pneumonia
[c] Includes COVID-19 pneumonia. Includes 2 fatalities from COVID-19 pneumonia and 1 fatality from pneumonia
[d] Includes preferred terms hemorrhage, intracranial hemorrhage, and gastrointestinal hemorrhage
[e] Includes preferred terms memory impairment, confusional state, encephalopathy, mental status changes
[f] Includes preferred terms second primary malignancy and nonmelanoma skin cancers. 1 fatality from metastatic malignant melanoma
[g] Includes preferred terms renal failure, chronic kidney disease, acute kidney injury
[h] Includes preferred terms supraventricular tachycardia, sinus tachycardia, atrial fibrillation

Clinically relevant adverse reactions in < 10% include vision changes, lower respiratory tract infection, urinary tract infection, herpesvirus infection, and tumor lysis syndrome.

Table 4 summarizes laboratory abnormalities in BRUIN.

Table 4: Select Laboratory Abnormalities (≥ 20%) That Worsened from Baseline in Patients with CLL/SLL Who Received Jaypirca

Laboratory Abnormality	Jaypirca[a] 200 mg once daily	
	All Grades (%)	**Grade 3 or 4 (%)**
Hematology		
Neutrophil count decreased	63	45
Hemoglobin decreased	48	19
Platelet count decreased	30	15
Lymphocyte count decreased	23	8
Chemistry		
Calcium decreased	40	2.8
Sodium decreased	30	0
ALT increased	23	2.8
AST increased	23	1.9
Creatinine increased	23	0
Lipase increased	21	7
Alkaline phosphatase increased	21	0

[a] The denominator used to calculate the rate varied from 83 to 108 based on the number of patients with a baseline value and at least one post-treatment value.

Grade 4 laboratory abnormalities in > 5% of patients included neutrophils decreased (23%).

Lymphocytosis: Upon initiation of Jaypirca, a temporary increase in lymphocyte counts (defined as absolute lymphocyte count increased ≥ 50% from baseline and a post-baseline value ≥ 5,000/μL) occurred in 64% of CLL/SLL patients in BRUIN. The median time to onset of lymphocytosis was 1.1 weeks, with 75% of cases occurring within 1.1 weeks, and the median duration was 19 weeks.

DRUG INTERACTIONS

Effect of Other Drugs on Jaypirca

Strong CYP3A Inhibitors: Pirtobrutinib is a CYP3A substrate. Concomitant use of Jaypirca with a strong CYP3A inhibitor increased pirtobrutinib systemic exposure, which may increase the risk of Jaypirca adverse reactions. Avoid concomitant use of strong CYP3A inhibitors during treatment with Jaypirca. If concomitant use of strong CYP3A inhibitors is unavoidable, reduce the Jaypirca dosage *[see Dosage and Administration]*.

Strong or Moderate CYP3A Inducers: Concomitant use of Jaypirca with a strong or moderate CYP3A inducer decreased pirtobrutinib systemic exposure, which may reduce Jaypirca efficacy. Avoid concomitant use of Jaypirca with strong or moderate CYP3A inducers. If concomitant use of moderate CYP3A inducers is unavoidable, increase the Jaypirca dosage *[see Dosage and Administration]*.

Effect of Jaypirca on Other Drugs

Sensitive CYP2C8, CYP2C19, CYP3A, P-gp, or BCRP Substrates: Jaypirca is a P-gp inhibitor, a moderate CYP2C8 and BCRP inhibitor, and a weak CYP2C19 and CYP3A inhibitor. Concomitant use of Jaypirca with sensitive P-gp, CYP2C8, BCRP, CYP2C19, or CYP3A substrates increased their plasma concentrations, which may increase the risk of adverse reactions related to these substrates for drugs which are sensitive to minimal concentration changes. Follow recommendations for sensitive CYP2C8, CYP2C19, CYP3A, P-gp, or BCRP substrates provided in their approved product labeling.

USE IN SPECIFIC POPULATIONS

Pregnancy

Risk Summary
Based on findings from animal studies, Jaypirca can cause fetal harm when administered to a pregnant woman. There are no available data on Jaypirca use in pregnant women to evaluate for a drug-associated risk. In an animal reproduction study, administration of pirtobrutinib to pregnant rats during organogenesis resulted in adverse developmental outcomes, including structural abnormalities, altered fetal growth, and embryo-fetal mortality, at maternal exposures approximately 3-times those in patients at the recommended daily dose of 200 mg (see *Data*). Advise pregnant women of the potential risk to a fetus.

The background risk in the U.S. general population of major birth defects is 2% to 4% and of miscarriage is 15% to 20% of clinically recognized pregnancies.

Data
Animal Data: In an embryo-fetal development study in rats, pregnant animals were administered oral doses of pirtobrutinib at up to 500 mg/kg twice daily during the period of organogenesis. Doses ≥ 375 mg/kg twice daily caused decreased fetal body weights and increased incidence of malformations and variations in the urinary tract (including absent or abnormal ureters and kidneys), reproductive tract (malpositioned ovaries and misshapen uterus), and bone (misshapen sternebrae). At 500 mg/kg twice daily, total resorption was observed. At 375 mg/kg twice daily in rats, the maternal systemic exposures (AUC) were approximately 3 times the human exposure at 200 mg once daily.

Lactation

Risk Summary
There are no data on the presence of pirtobrutinib in human milk or the effects on the breastfed child or milk production. Because of the potential for serious adverse reactions in the breastfed child, advise women not to breastfeed during treatment with Jaypirca and for one week after the last dose.

Females and Males of Reproductive Potential: Based on findings from animal studies, Jaypirca can cause fetal harm when administered to a pregnant woman *[see Use in Specific Populations]*.

Pregnancy Testing
Verify pregnancy status in females of reproductive potential prior to initiating Jaypirca.

Contraception
Females: Advise females of reproductive potential to use effective contraception during treatment with Jaypirca and for one week after the last dose.

Pediatric Use: Safety and effectiveness of Jaypirca have not been established in pediatric patients.

Geriatric Use: Of the patients with MCL who received the 200 mg dose of Jaypirca in BRUIN, 93 (78%) were 65 years of age and older and 39 (33%) were 75 years and older. Clinical studies of Jaypirca did not include sufficient numbers of patients with MCL who were less than 65 years of age to determine whether older patients respond differently from younger adult patients. Of the patients with CLL/SLL who received the 200 mg once daily dose of Jaypirca in BRUIN, 68 (63%) were 65 years of age and older and 21 (19%) were 75 years and older. No overall differences in effectiveness were observed between younger and older patients.

In the pooled safety population in patients with hematologic malignancies, 401 (68%) were 65 years of age and older, while 154 (26%) were 75 years of age and older. Patients aged 65 years and older experienced higher rates of Grade 3 and higher adverse reactions and serious adverse reactions compared to patients who were less than 65 years of age.

Renal Impairment: Severe renal impairment (eGFR 15-29 mL/min) increases pirtobrutinib exposure. Reduce the Jaypirca dosage in patients with severe renal impairment *[see Dosage and Administration]*. No dosage adjustment of Jaypirca is recommended in patients with mild (60-89 mL/min) or moderate (30-59 mL/min) renal impairment.

Hepatic Impairment: No dosage adjustment of Jaypirca is recommended in patients with mild hepatic impairment (total bilirubin ≤ upper limit of normal (ULN) and aspartate aminotransferase (AST) > ULN or total bilirubin > 1 to 1.5 × ULN and any AST), moderate hepatic impairment (total bilirubin > 1.5 to 3 × ULN and any AST), or severe hepatic impairment (total bilirubin > 3 × ULN and any AST).

Jaypirca® (pirtobrutinib) tablets, for oral use PT HCP BS JUN2024

DOSAGE AND ADMINISTRATION

Recommended Dosage: The recommended dosage of Jaypirca is 200 mg orally once daily until disease progression or unacceptable toxicity. Advise patients of the following:

- Swallow tablets whole with water. Do not cut, crush, or chew tablets.
- Take Jaypirca at the same time each day. Jaypirca may be taken with or without food.
- If a dose of Jaypirca is missed by more than 12 hours, do not make up the dose and take the next dose as scheduled.

Dosage Modifications for Adverse Reactions: Recommended dosage modifications of Jaypirca for adverse reactions are presented in the table below *[see Warnings and Precautions]*.

Recommended Dosage Modification of Jaypirca for Adverse Reactions

Adverse Reaction	**Occurrences Requiring Dose Modification**	**Modification** (Starting Dosage: 200 mg once daily)
• Grade 3 or greater non-hematologic toxicity [a] • Absolute neutrophil count < 1 to 0.5 x 10^9/L with fever and/or infection • Absolute neutrophil count < 0.5 x 10^9/L lasting 7 or more days • Platelet count < 50 to 25 x 10^9/L with bleeding • Platelet count < 25 x 10^9/L	**First occurrence**	Interrupt Jaypirca until recovery to Grade 1 or baseline; restart at original dosage (200 mg once daily)[a].
	Second occurrence	Interrupt Jaypirca until recovery to Grade 1 or baseline; restart at 100 mg once daily.
	Third occurrence	Interrupt Jaypirca until recovery to Grade 1 or baseline; restart at 50 mg once daily.
	Fourth occurrence	Discontinue Jaypirca.

Dose modification is not recommended for asymptomatic lymphocytosis. Asymptomatic lipase increase may not necessarily warrant dose modification.

[a] Evaluate the benefit-risk before resuming treatment at the same dose for a Grade 4 non-hematological toxicity.

Dosage Modifications for Patients with Severe Renal Impairment: For patients with severe renal impairment (eGFR 15-29 mL/min), reduce the Jaypirca dose to 100 mg once daily if the current dose is 200 mg once daily otherwise reduce the dose by 50 mg. If the current dosage is 50 mg once daily, discontinue Jaypirca *[see Use in Specific Populations]*. No dosage adjustment of Jaypirca is recommended in patients with mild to moderate renal impairment (eGFR 30-89 mL/min).

Dosage Modifications for Concomitant Use with Strong CYP3A Inhibitors: Avoid concomitant use of strong CYP3A inhibitors with Jaypirca *[see Drug Interactions]*. If concomitant use of a strong CYP3A inhibitor is unavoidable, reduce the Jaypirca dose by 50 mg. If the current dosage is 50 mg once daily, interrupt Jaypirca treatment for the duration of strong CYP3A inhibitor use. After discontinuation of a strong CYP3A inhibitor for 5 half-lives, resume the Jaypirca dose that was taken prior to initiating the strong CYP3A inhibitor.

Dosage Modifications for Concomitant Use with CYP3A Inducers: Avoid concomitant use of strong or moderate CYP3A inducers with Jaypirca *[see Drug Interactions]*. If concomitant use with moderate CYP3A inducers is unavoidable and the current dosage of Jaypirca is 200 mg once daily, increase the dose to 300 mg. If the current dosage is 50 mg or 100 mg once daily, increase the dose by 50 mg.

PATIENT COUNSELING INFORMATION: Advise the patient to read the FDA-approved patient labeling (Patient Information).

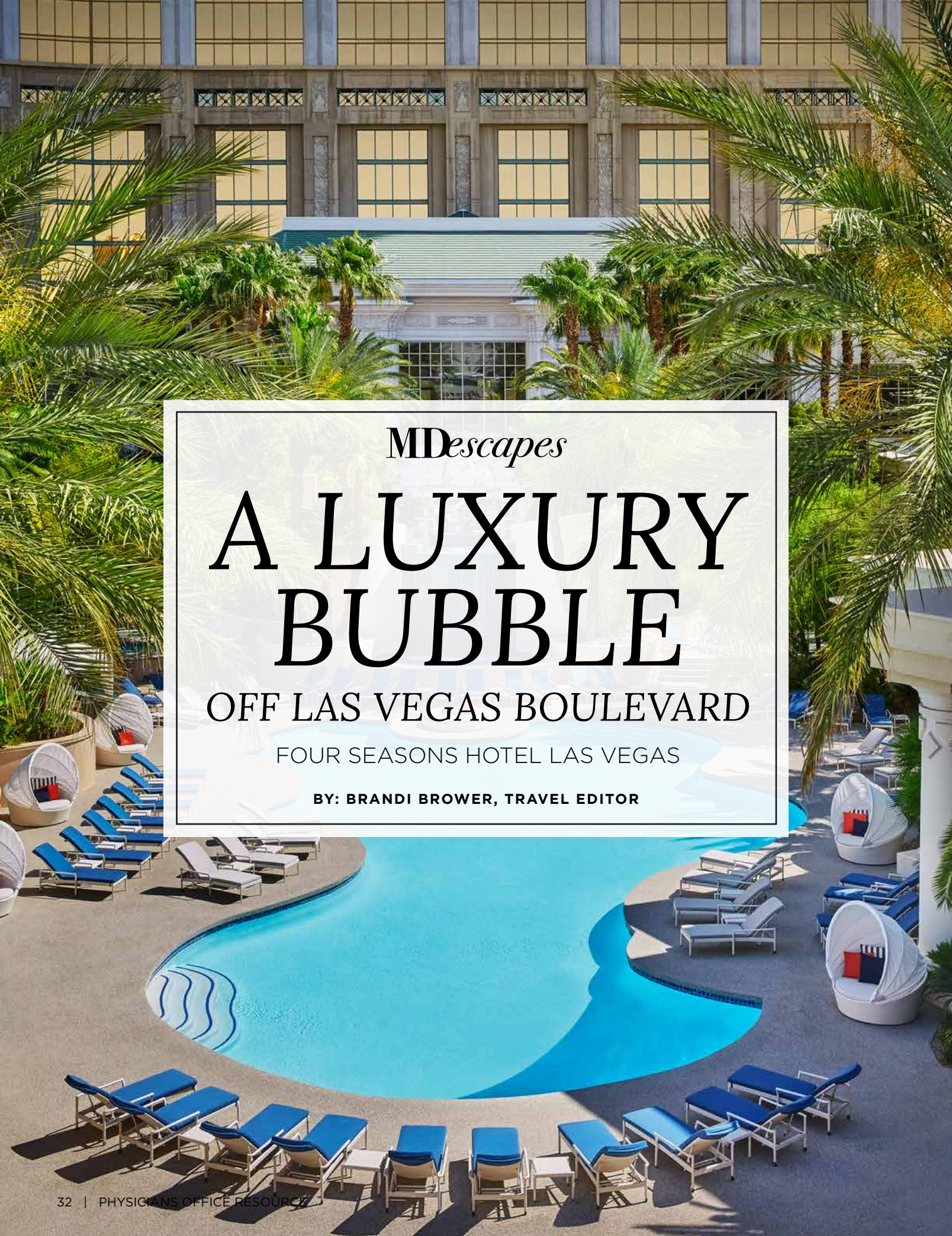
Additional information can be found at www.jaypirca.com

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PT HCP BS JUN2024

PP-PT-US-1002



MDescapes

A LUXURY BUBBLE

OFF LAS VEGAS BOULEVARD

FOUR SEASONS HOTEL LAS VEGAS

BY: BRANDI BROWER, TRAVEL EDITOR

I may be dating myself, but my core memory of Las Vegas was Circus Circus in the late 70s and early 80s in my youth. I would spend hours running around the midway of the carnival-themed casino while my parents dabbled in the delights of rolling the proverbial dice. Plastic cups overflowed with coins, and they sat on the bedside table of our hotel room. My mother's minuscule winnings on the slot machines conjured covetous thoughts as I wished I was old enough to try my luck. I remember the smell of smoke, wearing my favorite summer halter dress, and the dining experience at the budget-friendly buffet, realizing my adverse reaction to Chuck-A-Rama and Golden Corals my entire life stemmed from this gluttonous gallery of gorging under the Big Top.

My next recollection of the City of Lost Wages was traveling through Las Vegas during my college years, a fun pit-stop on the way to Spring Break in Southern California, pulling off of I-15 South to drive down Las Vegas Boulevard, to absorb the energy from the neon and observe the action from the crowded sidewalks, that was enough for me. The famous slogan: "What happens in Vegas, stays in Vegas" doesn't apply if you're merely driving down the strip and stopping at the 7-11 to buy snacks for the remainder of the road trip.

My knowledge of this renowned resort destination could have improved as an adult. It's ranked as one of the most visited cities in the U.S. -it is a fan favorite for over 40 million visitors annually. I had to find out what there was to offer besides the stereotypes created through cinema: gold-digging cocktail servers and down-on-their-luck gamblers, washed-up lounge singers, Elvis impersonators, or middle-of-the-night nuptials at the famous Little White Wedding Chapel. I wasn't looking for the cliche What happens here, stays here, "Hangover" experience. They say you haven't made it until you've played in Vegas. I was wondering what my definition of Viva Las Vegas would look like, but I was excited to find out.

My return to Sin City was going to be light on the sin. It's just not in my DNA. I have no real vices, but that doesn't mean I can't dip my toe in the pool. I arrived at the Four Seasons Hotel Las Vegas with an open mind. I liken it to a secret hideaway, so hidden that many people don't know of its existence. Located on the South end of the strip, it's part of the Mandalay property, a glittering tower that glows like a brick of gold when the hot desert sun sizzles upon it. My cab turns off the strip to a driveway lined with palm trees and gardens but very discreet in its design. An ornate fountain and large porte-cochère greet us, but no neon or flashy fanfare that one would expect in this city of lights. I'm formally welcomed by the bellman, who whisks us through to the lobby, where there is no wait on check-in. Las Vegas has 164,000 hotel rooms, making it the largest hospitality market in the U.S. It would take 288 years for one person to spend one night in every hotel room in Las Vegas. The largest property on the strip has over five thousand rooms. So you can imagine the reception lines to check in their guests.

The beauty of the Four Seasons Hotel Las Vegas is that it's like a boutique hotel among the giants, with 424 rooms, 81 of





which are suites, situated between the 35th and 39th floors of the Mandalay Bay Tower. It's one of the smallest hotels in Las Vegas, but with that designation comes the power of being present. Upon my arrival, my first impression was the staff's total presence, as if I was a dignitary they had been preparing to receive. From the warm welcome of the reception staff to the valet who showed me to my room, I felt genuine hospitality from minute one. Undoubtedly, the attentiveness and renowned Four Seasons service is one of the reasons it received the AAA Five-Diamond Award just six months after opening its doors. This award-winning hotel has garnered many accolades, including the most recent recognition of being named #1 in "Best Hotels in Las Vegas" and "Best Hotel" in Nevada" by U.S. News and World Report 2024.

My accommodations were on the 36th floor; as the team member set my luggage, my mouth was agape at the floor-to-ceiling wall of glass windows with a perfect view of the four-mile length of the strip. The glow of the setting sun is a natural contrast to the brightness of the artificial brilliance below. As the sun fades, the illumination intensifies, and so does my desire to



explore. But what the head wants, sometimes the body doesn't follow; my long travel day contributed to my decision to stay in and enjoy my beautiful room and take advantage of the extensive 24-hour in-room dining menu.

The room: a beautifully appointed space with subtle touches. A redesigned space to emulate the morning light of the Mojave Desert. The 500 square feet of modern comfort reflects Nevada's natural surroundings, calming creams and muted taupes with nods of lacquered and silver accents and black and white framed art pieces punctuating the room—subdued serenity. The marble bathroom is a tranquil retreat with a spacious walk-in shower and soaking tub—the mini-bar, cozy chairs, and dining table round off my expectations.

I'm ready to slip into my comfy Four Seasons robe and enjoy the Greek salad with Salmon, Mushroom Duxells with Ricotta, and an extra spoiler, a chocolate milkshake. Room service is a special treat; this late-night dining was prepared and delivered perfectly. The Four Seasons King-sized bed and cozy bedding are the remedy for a perfect night's sleep. My exploration of this glitzy town will have to wait until tomorrow.

The early bird catches the pastry at Press. Located in the first-floor lobby, by day, this lounge area is the perfect spot for grab-n-go breakfast items and coffee/tea selections. This chic and inviting quarter transforms from a place to enjoy a pick-me-up during the day to a happening hot spot for pre-dinner drinks and appetizers, pre-game libations, or perhaps a nightcap after an evening of fun on the strip. The bar's attractive basket weave metal base is a striking focal point, topped with a multifaceted marble bar top with modern brass accents. The style and comfort continue out of doors: couches, cozy chair groupings with fire pits under a trellis system, ambient bistro lighting, and surrounding trees lit up in white lights bring the party outside under the desert stars. If nothing else, it's an excellent place for glam people-watching while sipping on a craft cocktail. Unfortunately, I could not enjoy a featured event, The Bartenders Table Experience. This unique sensory journey takes you through crafting a well-balanced cocktail. In an hour-long interactive class with a skilled bartender, you are guided through the flavor wheel, learning the origin of spirits as you sip and experiment, concluding with a specialized concoction made exclusively in your honor.

After enjoying my delicious breakfast at Press, my first full day begins poolside. The exclusivity of this pool is what makes it an attractive retreat. At the base of the behemoth 43-story golden tower, this a high desert Shangri-la, a hidden gem awaits. There are plenty of cabanas, lounge chairs, umbrellas, thirsty towels, and staff to ensure your poolside pampering is complete. Palm trees outnumber the guests, a quiet enclave in contrast to other Las Vegas hotels where the pool party scene, EDM DJs blast the music, and vibrant atmosphere are the focus. The pool attendant listened attentively to my special request for seating and found me the perfect spot. The Pool Bar has a limited dining

In an hour-long interactive class with a skilled bartender, you are guided through the flavor wheel, learning the origin of spirits as you sip and experiment, concluding with a specialized concoction made exclusively in your honor.





menu with standard favorites. We enjoyed sharing the braised short ribs quesadilla with caramelized onion and a Jidori Chicken Caesar Salad, Grilled Chicken Breast, Sliced Avocado, Parmesan Frico, and Green Goddess Caesar Dressing. The best part about this panache pool is that you get the best of two worlds. If you decide to plunge into a splashier pool scene, all you need to do is go through a gate into Mandalay Bay's 11-acre aquatic playground. Being a guest at the Four Seasons Hotel Las Vegas gives you complete access to the extensive sister hotel's amenities, including a Lazy River, Wave Pool, adults-only pool, and pool clubs. I walked around the vast acreage but ultimately chose the quiet, liquid lounge of the Four Seasons.

Thankfully, I took advantage of the wealth of knowledge of all things Las Vegas and stopped to talk with one of the three concierges who were ready to assist. All made several suggestions and helped me plan my adventure for the night ahead, beginning with dinner onsite at Veranda. Walking to my room, I was impressed by the art installations covering the corridor on my way to the elevator. With football season upon us and the proximity of the Allegiant Stadium, home of the Las Vegas Raiders, steps from the Four Seasons Hotel Las Vegas, it made sense to invite artist John Knell as its artist-in-residence. His "Art of the End Zone" was fully displayed on the walls, lining the halls with color and exciting images of football favorites. Art is a focal point for the hotel's aesthetic, sometimes inspired by special events happening in the city; next up, works by artists Paul Oz and Manu Campa share the "Art of Speed" to commemorate the Las Vegas Grand Prix Race Weekend.

Veranda, modern American cuisine with Mediterranean flair, kicked off our evening. This restaurant is the only formal sit-down eatery on site, but plans are being finalized for an additional gastronomy hotspot. I enjoyed the Grilled Tenderloin, Romesco, Herb Garlic Butter, Roasted Shallots, Truffle Whipped Potato, Spicy Broccolini, Chili Oil, Lemon, and Garlic Crunch. And for dessert, a touch of whimsy with the Cloudtini, which consisted of Chocolate, Vanilla, Strawberry Gelato, NY Cheesecake, Brownies, Vanilla Bean Chantilly, Wafer, Hot Fudge, and Cotton Candy. Leave it to the pastry chefs of Four Seasons to curate such a fanciful creation. We dined outside on the veranda of Veranda, enjoying the warm breezes and dusk light almost as much as the cuisine.

We used the house car, a large black SUV, to take us out on the town. What a lovely perk the hotel provides if your destination is within two miles of the property. When the sun sets and the nightlife lights up, the streets get filled with cabs and Uber/Lyft drivers. We tipped the driver well, as it was a challenge to jockey around the double-parked cars and crowds of people making their way to the Sphere. The venue, just completed September 2023, has quickly become an iconic fixture in the Las Vegas landscape, with the building's exosphere featuring a 580,000-square-foot LED display, which comprises 1.23 million puck-shaped LEDs spaced 8 inches apart. Visuals displayed on the exosphere included a Halloween jack-o'-lantern, a Christmas snow globe, and a funny yellow emoji face, but this night, it displayed The Eagles band lettering. The famous group, formed in the 1970s, has a residency at the Sphere into early 2025. It was a lucky break to find tickets for what has been on my bucket list for years. During the concert, Eagles guitarist Joe Walsh said, "I had a lot more fun being twenty in the 70s than I am being seventy in the 20s, but I guess it will all figure itself out." The entire show was incredible, just what you'd expect from the city known as the Entertainment Capital of the World.





I am still determining my definition of Viva Las Vegas. But the next time I come to Sin City, I'll check into my little lux bubble off Las Vegas Boulevard.

We decided to walk back to our hotel after the concert. The swarm of 20,000 fans leaving the Sphere and pouring onto the strip was something to be part of. The bridge over to the Venetian, through the casino, then back out onto the strip, back through another casino, back out onto the strip... the sidewalks are barricaded for some unknown reason, which forces you to go in and out of many hotels along the strip to bypass blocked passageways. Then it hit me. The smoke, ambient noise pollution, and congestion were the epicenter of the Las Vegas spectacle. When we arrived back at the Four Seasons Hotel, our quiet refuge in a sea of chaos, walking into the gaming-free, smoke-free sanctuary at the southern end of the strip was like coming home. The exhale was audible from both of us as we entered our oasis of refuge and respite. It was eye-opening to experience the frenetic energy and glitzy excitement in the center of Sin City. But it was refreshing to return to this particular property's relaxation and peaceful ambiance, quiet, classy, and comforting. I sound like Joe Walsh, and I'm in my 70s (which I'm not), just trying to figure it all out.

The beauty of this little bubble of luxury is that you can have your casino cake and eat it, too. By pressing the "C" for the casino when in the Four Seasons elevator, you'll stop at the vestibule, where a door gets you into the Mandalay Bay hotel. All the amenities, including over two dozen bars, cafes and restaurants, gaming, shopping, and entertaining shows, are right next door. The Four Seasons interchange with Mandalay Bay allows you to conveniently charge anything to your hotel room. After you sell your soul to the slot machines, you can return through the private passageway via the touch of your room key and return home to your beautiful bubble.

The weekend brunch at Veranda is one of the most popular in Las Vegas. After indulging in classic fare and some welcomed additions, it was no surprise that this is a favorite for feasting on the weekend. The layout was perfect: the omelet bar, pastry table, salads and charcuterie, shrimp cocktail and smoked salmon, fruit assortment, yogurt, parfait and chia pudding, cereals and oatmeal, breakfast meats and potatoes. Some unique offerings: pork and shrimp shumai, cheesesteak boa buns, cauliflower mac and cheese, bacon jam and brie quiches, short rib hash, shrimp and grits, pumpkin pancakes, mascarpone cheese blintzes, and the homemade donut station were standouts. After all of that, how can one stand up? I didn't taste test everything, but I'm confident that, with the outstanding reputation of the Four Seasons, everything was delicious.

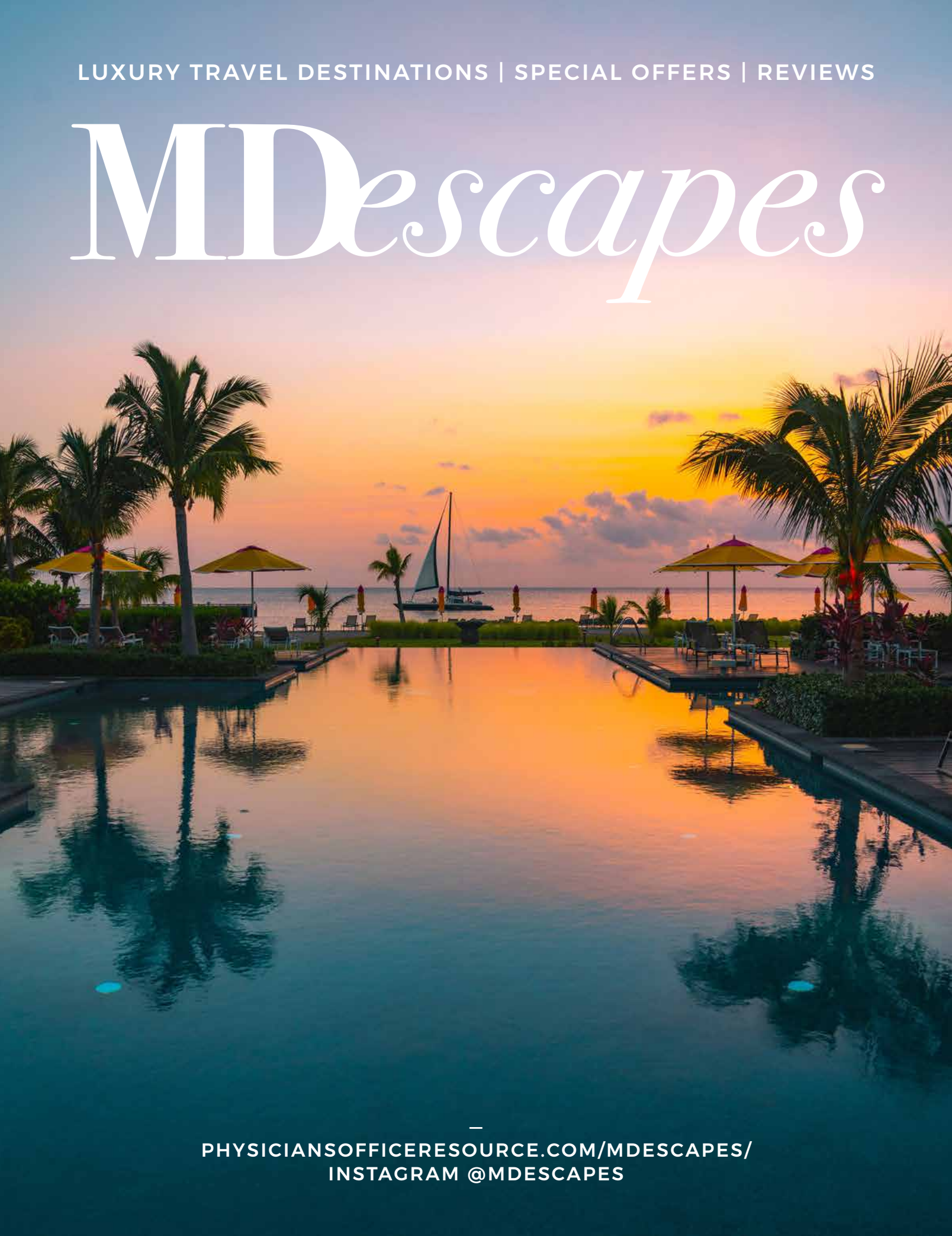
The Spa's reputation at the Four Seasons Hotel Las Vegas is five stars. Luxury and seclusion continue in this award-winning facility. With unique treatments and gorgeous surroundings, a self-care splurge should be on everyone's list when visiting Vegas. The fitness center overlooks the pool and offers top-of-the-line machines and equipment to help you work off your brunch. When seeking adventure outside the city limits, there are many exclusive activities curated by Four Seasons Hotel Las Vegas, such as Pink Jeep tours, kayak tours, and several unique helicopter tours if you choose to leave the bubble.

As the bellman packed my luggage into the waiting cab to take me on the short drive to the airport, I pondered on my preconceived notions about Las Vegas and realized some cliches weren't always true. I saw no gold-digging cocktail servers while staying at the Four Seasons Hotel Las Vegas. Instead, I found all the staff warm, amiable, and genuinely trying to meet my needs. Not all buffets are Circus Circus buffets; the brunch at Veranda was exceptional. As for entertainment, I heard no washed-up lounge singers but skilled professionals sharing their talents. I did, however, see one Elvis impersonator.

Ultimately, I am still determining my definition of Viva Las Vegas. But the next time I come to Sin City, I'll check into my little lux bubble off Las Vegas Boulevard.

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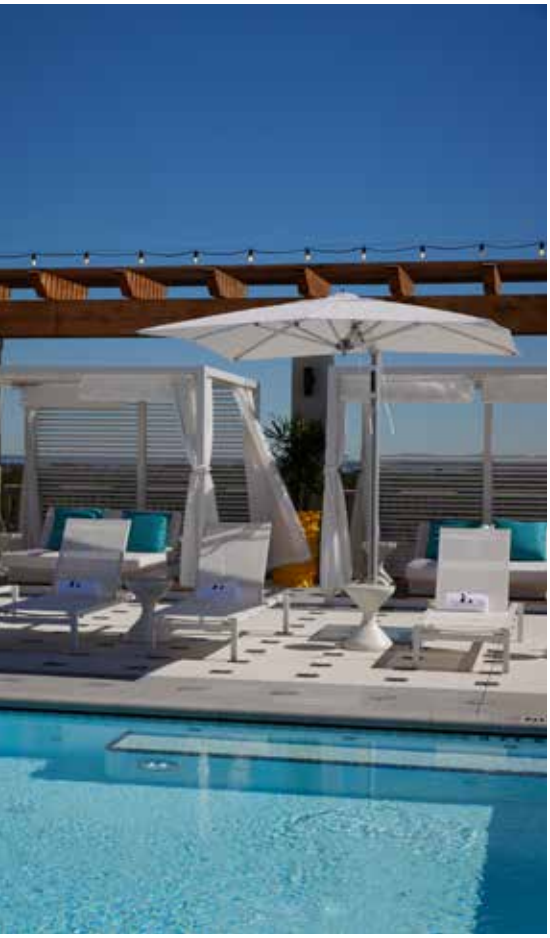
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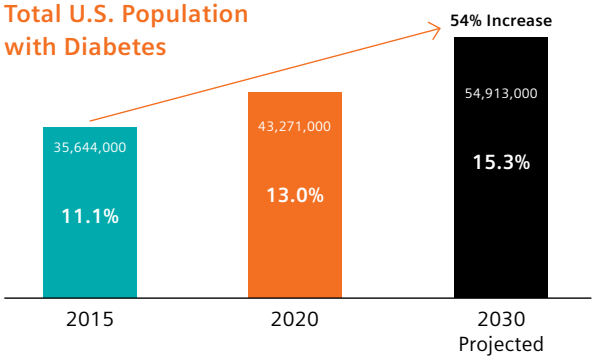
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1. Rowley, William R et al. "Diabetes 2030: Insights from Yesterday, Today, and Future Trends." Population health management vol. 20,1 (2017): 6-12. doi:10.1089/pop.2015.0181.

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