2022 | Issue 9

Physicians office Resource

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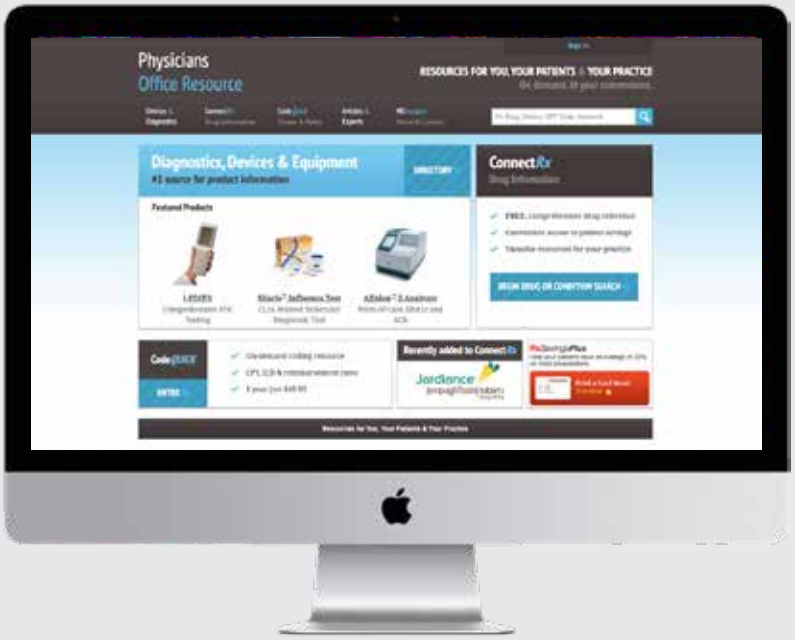
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Many epidemiologists agree that a combination of both a new COVID-19 surge and a true influenza epidemic winter season in the U.S. is possible, if not likely.

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PAGING ALL RESIDENTS: WHO'S LOOKING OUT FOR YOUR FINANCIAL WELLNESS?

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PREPARING FOR THE COMING COVID-19 AND INFLUENZA WINTER SEASON

BY JOHN D. TAMERIUS, PH.D. AND JHOBE STEADMAN, PH.D.

The Secretary of Health & Human Services (HHS) declared a Public Health Emergency on Jan. 31, 2020. Congress followed a few weeks later on March 13, 2020 with the declaration of a National Emergency and granted $25 billion to HHS to take immediate steps to accelerate the development of vaccines, therapeutics and diagnostic tests. Five weeks later the National Institutes of Health (NIH) created the Rapid Acceleration of Diagnostics Initiative (RADx) and Quidel® Corporation was one of several companies that received scientific and regulatory guidance and funding to help meet the profound need of the American people during this emergency. Despite the criticisms commonly heard, a tremendous amount was accomplished in record time, including the creation of effective vaccines, the development of diagnostic antigen and molecular tests for diagnosis of SARS-CoV-2 and for the advancing development of therapeutic agents---all in less than one year.

Quidel, partly with RADx support, was the first diagnostic firm to receive the FDA's Emergency Use Authorization (EUA) for a rapid antigen test in the U.S.—the fluorescence immunoassay (FIA) called Sofia® SARS Antigen FIA for point-of-care (POC) use in the physician's office lab. A few months later, Quidel was also the first to receive an EUA for a multiplex antigen assay, Sofia 2® Flu + SARS Antigen FIA, for simultaneous testing for SARS-CoV-2, Influenza A, and influenza B from one swab specimen. As shown in **Table 1**, within one year after the declaration of our National Emergency, Quidel had received EUAs for 8 different assays, including EUAs for the QuickVue SARS Assay (a 10-minute, visually read dipstick assay), one for POC and one for at-home use and two molecular assays.

This unprecedented work by government and industry required time. The pandemic was spreading quickly around the world and the public had very little to no protection. Fortunately, non-pharmaceutical interventions (NPI) were quickly introduced and promoted widely across the United States. Wherever lock downs, school closures, reduced face-to-face interaction, mask wearing, reduced mobility,

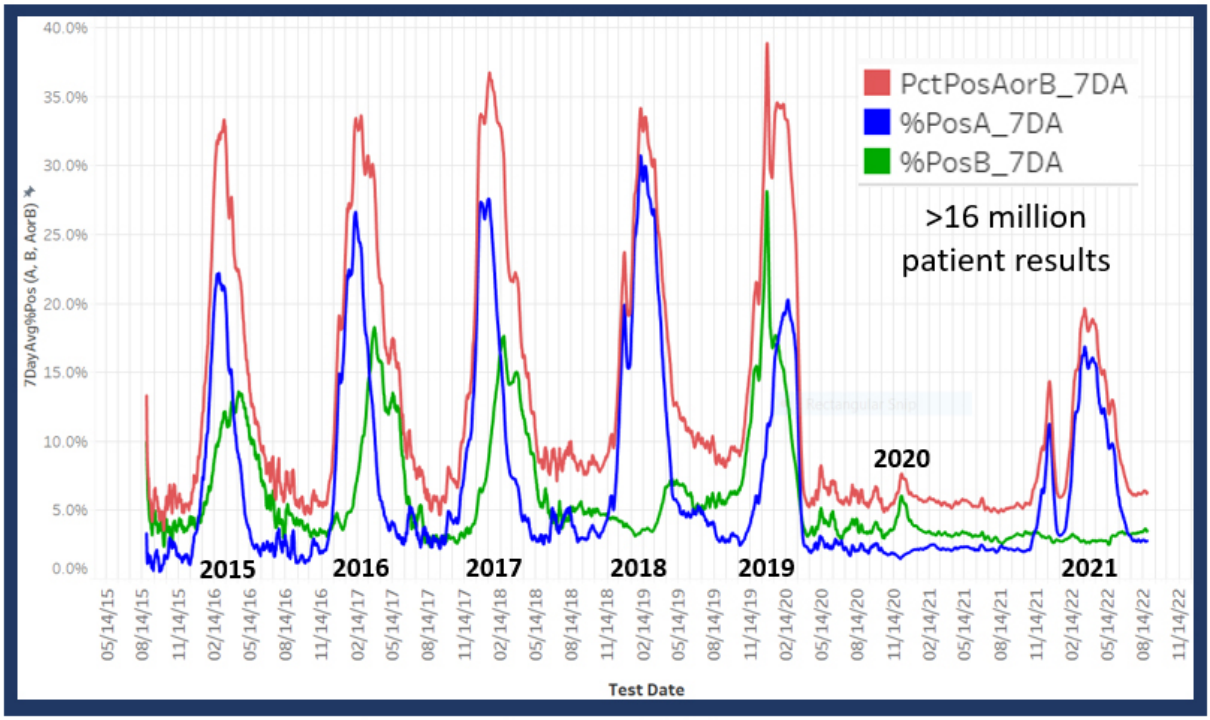
Table 1
QuidelOrtho™ SARS-CoV-2 Diagnostics History
POC and OTC / At-Home Tests

Event	Status	Date
SARS-CoV-2 identified	---	11/17/19
Congress declares National Emergency	---	3/13/20
Lyra® SARS-CoV-2 Assay	EUA / POC / Hospital / Molecular Assay	3/17/20
Sofia® SARS Antigen FIA	EUA / POC / First rapid antigen test / 15 minutes	5/8/20
Lyra Direct SARS-CoV-2 Assay	EUA / POC / Hospital / Molecular Assay	5/18/20
Sofia 2 Flu + SARS Antigen FIA	EUA / POC / First multiplex rapid antigen test / 15 minutes	10/2/20
QuickVue® SARS Antigen Test	EUA / POC / Visually-read dipstick / 10 minutes	10/17/20
Solana® SARS-CoV-2 Assay	EUA / POC / Hospital / Molecular Assay (HDA)	12/23/20
QuickVue At-Home OTC COVID-19 Test	EUA / OTC / Prescription Use Only / First OTC test	3/1/21
QuickVue At-Home OTC COVID-19 Test	EUA / OTC / 10 minutes / Visually read	3/31/21

and working at home occurred, there were significantly reduced hospitalizations and deaths. This protection by NPI, although not absolute, bought research scientists and industry time while vaccines, COVID-19 therapeutics and diagnostics were being developed.

While our government agencies and industries were working on these goals, NPI also reduced the incidence of certain other respiratory infections, including that of influenza Types A and B. **Figure 1** shows the course of influenza in the United States from September 2015 to the present and reveals the profound impact of NPI on influenza incidence. Note the data depicted in this figure are derived from over 16 million patient de-identified test results that were automatically transmitted to Quidel by users of Sofia and Sofia 2 for surveillance, using a system called Virena®. Virena

Figure 1
USA Influenza Positivity Rate by Sofia® and Sofia 2 FIAs
8/25/15 to 8/25/22



Results automatically transmitted daily from FIAs by Virena®

information is updated daily and is automatically and securely shared with the CDC and readily available to Quidel customers on MyVirena.com. Virena is also a no charge service provided to all Sofia and Sofia 2 users.

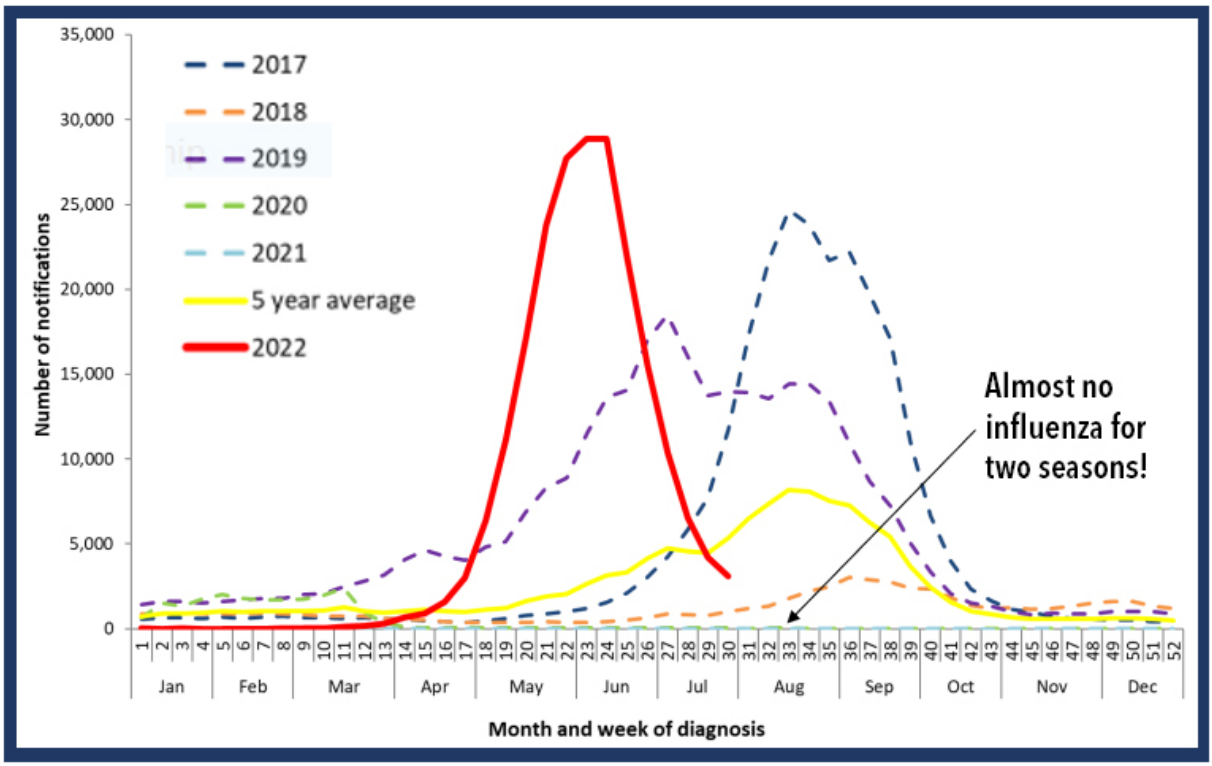
After the abrupt end of the 2019-2020 season, there followed 18 months during which the combined influenza positive rates for influenza types A and B rarely exceeded 6%. Then last winter, 2021-2022, there were two influenza surges; both failed to approach the positivity rates and the duration seen in the previous 5 epidemic seasons. Both surges this past winter also ended abruptly, timed closely to the arrivals of Omicron in Dec. 2021 and of the BA.4 and BA.5 Omicron subvariants that became dominant after January 2022. This dramatic decline in influenza is believed largely due to the implementation of NPI that were needed to reduce the spread of COVID-19 until other measures could be taken.

A large portion of our population is now feeling exhausted after doing their best to address this pandemic for over two and a half years. NPI use is on the decline. Omicron and its direct subvariant offspring are much less virulent than their predecessors, further reducing the concern about being infected, thus further reducing interest or willingness to be vaccinated or to use NPI. In addition, much of the testing for COVID-19 is now done at home and most at-home results are not reported, reducing the awareness and concern of COVID-19 in their communities. On top of this, promotional activities for NPI have diminished.

In addition to enabling COVID-19 infections to more easily spread and persist in our population, failing to use NPI will likely increase the risk of a stronger influenza season this coming winter, perhaps even resulting in a more traditional season with epidemic levels of influenza rather than the "failed" surges* we experienced last winter. Enhancing this risk, only 52% of the U.S. population is vaccinated against influenza. Even many of those who have gotten routine vaccinations for influenza annually, have possibly skipped the last year or two given the widely known low influenza incidence and, with the passing of time, whatever immunity they might have had before the advent of the COVID-19 pandemic has likely wanned. So, the risks for significant influenza season seem higher than at any time since the winter of 2019.

We often look to the southern hemisphere for clues because their winter precede ours by half a year. Careful examination of **Figure 2** shows the profound decline in incidence of influenza in their two previous winters, just like in the USA. This winter there was a pronounced influenza epidemic and the worst influenza in May in Australia's history. Such events in the southern hemisphere are not absolute predictors of events

Figure 2
Confirmed Influenza Cases in Australia



From Australian Dept. of Health and Aged Care: Influenza Surveillance Report

in the northern hemisphere, but they rightfully raise further concern for this winter in North America.

Many epidemiologists agree that a combination of both a new COVID-19 surge and a true influenza epidemic winter season in the U.S. is possible, if not likely. Indeed, it appears that the annual influenza epidemic almost broke out last 2021-2022 winter with the two surges as we discussed above. The use of NPI was likely strong enough to possibly slow or halt its spread. This may not be the case this year given the exhaustion of our populace, the low vaccination rate, reopening of schools, beginning of return to workplaces, ongoing decline in NPI use, and overall diminution of herd immunity.

Unfortunately, the signs and symptoms for infections by SARS-CoV-2 and influenza are very similar **(Table 2)**. Given that there are now effective treatments for both influenza and COVID-19, it seems imperative that steps are taken to test for all three pathogens when patients present with such symptoms—especially in communities where both COVID-19 and Influenza are likely circulating at the same time.

As mentioned in **Table 1**, Quidel was the first company to receive an EUA for a multiplex antigen detection assay in

Table 2
Similarity of COVID-19 and Influenza Illness Symptoms

Symptom	COVID-19	Influenza
Fever or chills	X	X
Cough	X	X
Sore throat	X	X
Runny nose or congestion	X	X
Shortness of breath	X	—
Difficulty breathing	X	—
Muscle or body aches	X	X
Headaches	X	X
Fatigue	X	X
Nausea or vomiting	X	X
New loss of taste or smell	X	—
Diarrhea	X	X

"In addition to enabling COVID-19 infections to more easily spread and persist in our population, failing to use NPI will likely increase the risk of a stronger influenza season this coming winter..."

the United States. This CLIA waived test provides a result in 15 minutes with a simple nasal swab and is available for most labs. For busy clinics it provides flexible workflows, requiring limited hands-on-time, including a batch testing mode that allows processing and testing of several patient samples at a time. Getting daily reports from your local public health office or by accessing Quidel's on-line reporting system (MyVirena.com) could indicate whether only COVID-19 or Influenza are in your community. If this is the case, options in **Table 1** provide you practical and available alternatives available from Quidel.

With decline in use of NPI, reduced herd immunity, only 52% influenza vaccination rate (persons > 6 months of age), and given the hint from Australia **(Figure 2)**, as well as the two attempts by influenza to break out in the United States more broadly last December and again in February **(Figure 1)**, it is best to begin to prepare now for the return of influenza and potentially at the same time when COVID-19 is surging or otherwise maintaining a moderate incidence level. Rapid diagnosis is critically important as patients, especially high-risk ones, can be treated successfully with specific antivirals that have been developed for each of the pathogens—provided they are administered early, preferably starting within 2 days after symptom onset for influenza and within 5 days after symptom onset for COVID-19.
To prepare for the likely resurgence of influenza, perhaps at the same time as a new surge of COVID-19, we encourage physicians to do the following:

Monitor surveillance data for incidence of COVID-19 and influenza in your state, county and community. This could be accomplished by monitoring public health reports and/or, for users of Sofia and Sofia 2, by monitoring the status of both viruses' incidence by readily accessing Virena data on Quidel's MyVirena.com.

Make sure that your clinic provides COVID-19 and influenza test results to your local and regional public health agencies, so that they can provide a more complete status update for you and others.

Actively support vaccinations, including boosters with the newly approved vaccine(s) covering the new SARS-CoV-2 Omicron subvariants.

Encourage your staff and patients to get the new season's influenza vaccines that are now available. Patients older than 65 years, should get the special influenza vaccine designed for them. Given that the influenza season started so early in Australia, it could do the same here, so providing the flu vaccinations for yourself, staff, and your patients by the end of September could be best.

Encourage the use of NPI, especially at least through this winter, and especially reinforced by your knowledge through surveillance of incidence of both pathogens circulating in your community. The data show without question that NPI reduces COVID-10 and Influenza infections and spread.

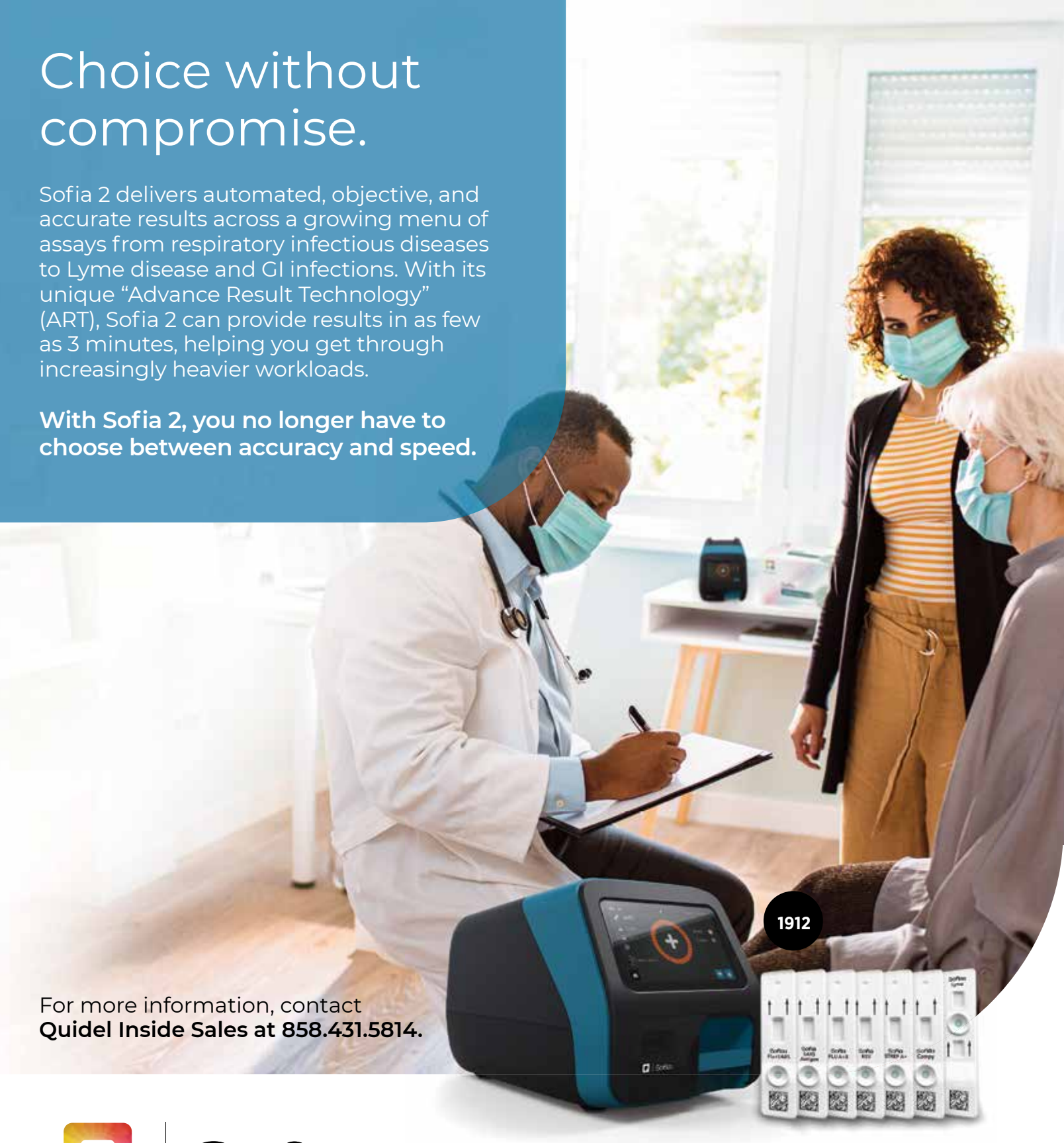
Be prepared for testing for both SARS-CoV-2 and Influenza. All three viruses are likely to be circulating in your community this winter—potentially at the same time. Using Sofia 2 SARS + Flu FIA may be the best choice for you, as it screens for all three viruses at once with only one patient nasal swab sample required.

**Failed "surges". Even though the surges this past winter did not constitute a typical influenza epidemic, the CDC has reported that between Oct. 2021, and June 11, 2022, there were 8 million to 13 million influenza cases, 82,000 to 170,000 hospitalizations, and 5,000 to 14,000 deaths In the United States. We must all take steps now to prepare for the coming COVID-19 and Influenza winter season.*

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Sofia 2 delivers automated, objective, and accurate results across a growing menu of assays from respiratory infectious diseases to Lyme disease and GI infections. With its unique "Advance Result Technology" (ART), Sofia 2 can provide results in as few as 3 minutes, helping you get through increasingly heavier workloads.

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RSV | Strep A+ | Lyme | Campylobacter

*THESE TESTS ARE AVAILABLE FOR SALE IN THE USA UNDER EMERGENCY USE AUTHORIZATION. These tests have not been FDA cleared or approved, but have been authorized by the FDA under an Emergency Use Authorization (EUA) for use by authorized laboratories for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens. These assays are only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of *in vitro* diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless authorization is terminated or revoked sooner.

AD10102100EN00 (03/22)



TAKE A STAND FOR LONGER SURVIVAL

In Relapsed or Refractory FLT3m+ AML,* XOSPATA Is the Only FDA-Approved Targeted Monotherapy to Deliver Superior Overall Survival† vs Salvage Chemotherapy[1,2]

36% **reduced risk of death with XOSPATA** (n=247)[1]

vs salvage chemotherapy (n=124)
HR=0.64 (95% CI: 0.49, 0.83); *P*=0.0004

9.3 months **median OS with XOSPATA** (95% CI: 7.7, 10.7)[1]

vs 5.6 months with salvage chemotherapy (95% CI: 4.7, 7.3)

Gilteritinib (XOSPATA) sets a standard in relapsed or refractory FLT3m+ AML[1,3]
Gilteritinib (XOSPATA) is the ONLY Category 1 recommendation in the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for patients with relapsed or refractory FLT3m+ AML[3]

XOSPATA was evaluated in a Phase 3, open-label, multicenter, randomized clinical trial compared with a prespecified salvage chemotherapy in adult patients with relapsed or refractory FLT3m+ AML.[1,4] Prespecified salvage chemotherapy regimens included high-intensity combinations MEC‡ and FLAG-IDA§ and low-intensity regimens LDAC‖ and AZA.[1¶]

*FLT3 mutation status: *FLT3-ITD*, *FLT3-TKD*, and *FLT3-ITD-TKD*.[1]

†The OS endpoint was measured from the date of randomization until death by any cause in the final analysis, which included 371 patients randomized 2:1 to receive XOSPATA or a prespecified salvage chemotherapy regimen.[1]

‡MEC: mitoxantrone 8 mg/m^2, etoposide 100 mg/m^2, and cytarabine 1000 mg/m^2 once daily by IV infusion Days 1 to 5.[1]

§FLAG-IDA: granulocyte colony-stimulating factor 300 mcg/m^2 once daily by SC injection Days 1 to 5, fludarabine 30 mg/m^2 once daily by IV infusion Days 2 through 6, cytarabine 2000 mg/m^2 once daily by IV infusion Days 2 through 6, idarubicin 10 mg/m^2 once daily by IV infusion Days 2 through 4.[1]

‖LDAC: cytarabine 20 mg twice daily by SC injection or IV infusion for 10 days.[1]

¶AZA: azacitidine 75 mg/m^2 once daily by SC injection or IV infusion for 7 days.[1]

AML=acute myeloid leukemia; CI=confidence interval; FDA=Food and Drug Administration; FLT3=FMS-like tyrosine kinase 3; HR=hazard ratio; ITD=internal tandem duplication; IV=intravenous; LDAC=low-dose cytarabine; m+=mutation-positive; NCCN=National Comprehensive Cancer Network; OS=overall survival; SC=subcutaneous; TKD=tyrosine kinase domain.

References: 1. XOSPATA [package insert]. Northbrook, IL: Astellas Pharma US, Inc. **2.** Ballesta-López O, Solana-Altabella A, Megías-Vericat JE, Martínez-Cuadrón D, Montesinos P. Gilteritinib use in the treatment of relapsed or refractory acute myeloid leukemia with a FLT3 mutation. Future Oncol (Epub) 09-25-2020. **3.** Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Acute Myeloid Leukemia V.1 2022. © National Comprehensive Cancer Network, Inc. 2022. All rights reserved. Accessed 12-03-2021. To view the most recent and complete version of the guideline, go online to NCCN.org. NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way. **4.** Astellas. XOSPATA. Data on File.

Scan the QR code to visit **XospataHCP.com** for more information

Please see adjacent pages for Brief Summary of Full Prescribing Information, including BOXED WARNING.

INDICATION

XOSPATA is indicated for the treatment of adult patients who have relapsed or refractory acute myeloid leukemia (AML) with a FMS-like tyrosine kinase 3 (FLT3) mutation as detected by an FDA-approved test.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

XOSPATA is contraindicated in patients with hypersensitivity to gilteritinib or any of the excipients. Anaphylactic reactions have been observed in clinical trials.

WARNING: DIFFERENTIATION SYNDROME

Patients treated with XOSPATA have experienced symptoms of differentiation syndrome, which can be fatal or life-threatening if not treated. Symptoms may include fever, dyspnea, hypoxia, pulmonary infiltrates, pleural or pericardial effusions, rapid weight gain or peripheral edema, hypotension, or renal dysfunction. If differentiation syndrome is suspected, initiate corticosteroid therapy and hemodynamic monitoring until symptom resolution.

WARNINGS AND PRECAUTIONS

Differentiation Syndrome (See BOXED WARNING) 3% of 319 patients treated with XOSPATA in the clinical trials experienced differentiation syndrome. Differentiation syndrome is associated with rapid proliferation and differentiation of myeloid cells and may be life-threatening or fatal if not treated. Symptoms and other clinical findings of differentiation syndrome in patients treated with XOSPATA included fever, dyspnea, pleural effusion, pericardial effusion, pulmonary edema, hypotension, rapid weight gain, peripheral edema, rash, and renal dysfunction. Some cases had concomitant acute febrile neutrophilic dermatosis. Differentiation syndrome occurred as early as 1 day and up to 82 days after XOSPATA initiation and has been observed with or without concomitant leukocytosis. If differentiation syndrome is suspected, initiate dexamethasone 10 mg IV every 12 hours (or an equivalent dose of an alternative oral or IV corticosteroid) and hemodynamic monitoring until improvement. Taper corticosteroids after resolution of symptoms and administer corticosteroids for a minimum of 3 days. Symptoms of differentiation syndrome may recur with premature discontinuation of corticosteroid treatment. If severe signs and/or symptoms persist for more than 48 hours after initiation of corticosteroids, interrupt XOSPATA until signs and symptoms are no longer severe.

Posterior Reversible Encephalopathy Syndrome (PRES) 1% of 319 patients treated with XOSPATA in the clinical trials experienced posterior reversible encephalopathy syndrome (PRES) with symptoms including seizure and altered mental status. Symptoms have resolved after discontinuation of XOSPATA. A diagnosis of PRES requires confirmation by brain imaging, preferably magnetic resonance imaging (MRI). Discontinue XOSPATA in patients who develop PRES.

Prolonged QT Interval XOSPATA has been associated with prolonged cardiac ventricular repolarization (QT interval). 1% of the 317 patients with a post-baseline QTc measurement on treatment with XOSPATA in the clinical trial were found to have a QTc interval greater than 500 msec and 7% of patients had an increase from baseline QTc greater than 60 msec. Perform electrocardiogram (ECG) prior to initiation of treatment with XOSPATA, on days 8 and 15 of cycle 1, and prior to the start of the next two subsequent cycles. Interrupt and reduce XOSPATA dosage in patients who have a QTcF >500 msec. Hypokalemia or hypomagnesemia may increase the QT prolongation risk. Correct hypokalemia or hypomagnesemia prior to and during XOSPATA administration.

Pancreatitis 4% of 319 patients treated with XOSPATA in the clinical trials experienced pancreatitis. Evaluate patients who develop signs and symptoms of pancreatitis. Interrupt and reduce the dose of XOSPATA in patients who develop pancreatitis.

Embryo-Fetal Toxicity XOSPATA can cause embryo-fetal harm when administered to a pregnant woman. Advise females of reproductive potential to use effective contraception during treatment with XOSPATA and for 6 months after the last dose of XOSPATA. Advise males with female partners of reproductive potential to use effective contraception during treatment with XOSPATA and for 4 months after the last dose of XOSPATA. Pregnant women, patients becoming pregnant while receiving XOSPATA or male patients with pregnant female partners should be apprised of the potential risk to the fetus.

ADVERSE REACTIONS

Fatal adverse reactions occurred in 2% of patients receiving XOSPATA. These were cardiac arrest (1%) and one case each of differentiation syndrome and pancreatitis. The most frequent (≥5%) nonhematological serious adverse reactions reported in patients were fever (13%), dyspnea (9%), renal impairment (8%), transaminase increased (6%) and noninfectious diarrhea (5%).

7% discontinued XOSPATA treatment permanently due to an adverse reaction. The most common (>1%) adverse reactions leading to discontinuation were aspartate aminotransferase increased (2%) and alanine aminotransferase increased (2%).

The most frequent (≥5%) grade ≥3 nonhematological adverse reactions reported in patients were transaminase increased (21%), dyspnea (12%), hypotension (7%), mucositis (7%), myalgia/arthralgia (7%), and fatigue/malaise (6%).

Other clinically significant adverse reactions occurring in ≤10% of patients included: electrocardiogram QT prolonged (9%), hypersensitivity (8%), pancreatitis (5%), cardiac failure (4%), pericardial effusion (4%), acute febrile neutrophilic dermatosis (3%), differentiation syndrome (3%), pericarditis/myocarditis (2%), large intestine perforation (1%), and posterior reversible encephalopathy syndrome (1%).

Lab Abnormalities Shifts to grades 3-4 nonhematologic laboratory abnormalities in XOSPATA treated patients included phosphate decreased (14%), alanine aminotransferase increased (13%), sodium decreased (12%), aspartate aminotransferase increased (10%), calcium decreased (6%), creatine kinase increased (6%), triglycerides increased (6%), creatinine increased (3%), and alkaline phosphatase increased (2%).

DRUG INTERACTIONS

Combined P-gp and Strong CYP3A Inducers Concomitant use of XOSPATA with a combined P-gp and strong CYP3A inducer decreases XOSPATA exposure which may decrease XOSPATA efficacy. Avoid concomitant use of XOSPATA with combined P-gp and strong CYP3A inducers.

Strong CYP3A inhibitors Concomitant use of XOSPATA with a strong CYP3A inhibitor increases XOSPATA exposure. Consider alternative therapies that are not strong CYP3A inhibitors. If the concomitant use of these inhibitors is considered essential for the care of the patient, monitor patient more frequently for XOSPATA adverse reactions. Interrupt and reduce XOSPATA dosage in patients with serious or life-threatening toxicity.

Drugs that Target 5HT2B Receptor or Sigma Nonspecific Receptor Concomitant use of XOSPATA may reduce the effects of drugs that target the 5HT2B receptor or the sigma nonspecific receptor (e.g., escitalopram, fluoxetine, sertraline). Avoid concomitant use of these drugs with XOSPATA unless their use is considered essential for the care of the patient.

P-gp, BCRP, and OCT1 Substrates Based on *in vitro* data, gilteritinib is a P-gp, breast cancer resistant protein (BCRP), and organic cation transporter 1 (OCT1) inhibitor. Coadministration of gilteritinib may increase the exposure of P-gp, BCRP, and OCT1 substrates, which may increase the incidence and severity of adverse reactions of these substrates. For P-gp, BCRP, or OCT1 substrates where small concentration changes may lead to serious adverse reactions, decrease the dose or modify the dosing frequency of such substrate and monitor for adverse reactions as recommended in the respective prescribing information.

SPECIFIC POPULATIONS

Lactation Advise women not to breastfeed during treatment with XOSPATA and for 2 months after the last dose.

astellas

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XOSPATA®
gilteritinib 40mg tablets

XOSPATA®
gilteritinib 40mg tablets

XOSPATA® (gilteritinib) tablets for oral use

The following is a brief summary of full Prescribing Information. Please see the package insert for full prescribing information.

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INDICATIONS AND USAGE

XOSPATA is indicated for the treatment of adult patients who have relapsed or refractory acute myeloid leukemia (AML) with a FMS-like tyrosine kinase 3 (FLT3) mutation as detected by an FDA-approved test.

DOSAGE AND ADMINISTRATION

Patient Selection

Select patients for the treatment of AML with XOSPATA based on the presence of FLT3 mutations in the blood or bone marrow. Information on FDA-approved tests for the detection of a FLT3 mutation in AML is available at http://www.fda.gov/CompanionDiagnostics.

Recommended Dosage

The recommended starting dose of XOSPATA is 120 mg orally once daily with or without food. Response may be delayed. In the absence of disease progression or unacceptable toxicity, treatment for a minimum of 6 months is recommended to allow time for a clinical response. Do not break or crush XOSPATA tablets. Administer XOSPATA tablets orally about the same time each day. If a dose of XOSPATA is missed or not taken at the usual time, administer the dose as soon as possible on the same day, and at least 12 hours prior to the next scheduled dose. Return to the normal schedule the following day. Do not administer 2 doses within 12 hours.

Dosage Modifications

Assess blood counts and blood chemistries, including creatine phosphokinase, prior to the initiation of XOSPATA, at least once weekly for the first month, once every other week for the second month, and once monthly for the duration of therapy. Perform electrocardiogram (ECG) prior to initiation of treatment with gilteritinib, on days 8 and 15 of cycle 1, and prior to the start of the next two subsequent cycles. Interrupt dosing or reduce dose for toxicities.

CONTRAINDICATIONS

XOSPATA is contraindicated in patients with hypersensitivity to gilteritinib or any of the excipients. Anaphylactic reactions have been observed in clinical trials.

WARNINGS AND PRECAUTIONS

Differentiation Syndrome

Of 319 patients treated with XOSPATA in the clinical trials, 3% experienced differentiation syndrome. Differentiation syndrome is associated with rapid proliferation and differentiation of myeloid cells and may be life-threatening or fatal if not treated. Symptoms and other clinical findings of differentiation syndrome in patients treated with XOSPATA included fever, dyspnea, pleural effusion, pericardial effusion, pulmonary edema, hypotension, rapid weight gain, peripheral edema, rash, and renal dysfunction. Some cases had concomitant acute febrile neutrophilic dermatosis. Differentiation syndrome occurred as early as 1 day and up to 82 days after XOSPATA initiation and has been observed with or without concomitant leukocytosis. Of the 11 patients who experienced differentiation syndrome, 9 (82%) recovered after treatment or after dose interruption of XOSPATA. If differentiation syndrome is suspected, initiate dexamethasone 10 mg IV every 12 hours (or an equivalent dose of an alternative oral or IV corticosteroid) and hemodynamic monitoring until improvement. Taper corticosteroids after resolution of symptoms and administer corticosteroids for a minimum of 3 days. Symptoms of differentiation syndrome may recur with premature discontinuation of corticosteroid treatment. If severe signs and/or symptoms persist for more than 48 hours after initiation of corticosteroids, interrupt XOSPATA until signs and symptoms are no longer severe.

Posterior Reversible Encephalopathy Syndrome (PRES)

Of 319 patients treated with XOSPATA in the clinical trials, 1% experienced posterior reversible encephalopathy syndrome (PRES) with symptoms including seizure and altered mental status. Symptoms have resolved after discontinuation of XOSPATA. A diagnosis of PRES requires confirmation by brain imaging, preferably magnetic resonance imaging (MRI). Discontinue XOSPATA in patients who develop PRES.

Prolonged QT Interval

XOSPATA has been associated with prolonged cardiac ventricular repolarization (QT interval). Of the 317 patients with a post-baseline QTc measurement on treatment with XOSPATA in the clinical trial, 1% were found to have a QTc interval greater than 500 msec and 7% of patients had an increase from baseline QTc greater than 60 msec. Perform electrocardiogram (ECG) prior to initiation of treatment with gilteritinib, on days 8 and 15 of cycle 1, and prior to the start of the next two subsequent cycles. Interrupt and reduce XOSPATA dosage in patients who have a QTcF >500 msec. Hypokalemia or hypomagnesemia may increase the QT prolongation risk. Correct hypokalemia or hypomagnesemia prior to and during XOSPATA administration.

Pancreatitis

Of 319 patients treated with XOSPATA in the clinical trials, 4% experienced pancreatitis. Evaluate patients who develop signs and symptoms of pancreatitis. Interrupt and reduce the dose of XOSPATA in patients who develop pancreatitis.

Embryo-Fetal Toxicity

Based on findings in animals and its mechanism of action, XOSPATA can cause embryo-fetal harm when administered to a pregnant woman. Advise females of reproductive potential to use effective contraception during treatment with XOSPATA and for 6 months after the last dose of XOSPATA. Advise males with female partners of reproductive potential to use effective contraception during treatment with XOSPATA and for 4 months after the last dose of XOSPATA. Pregnant women, patients becoming pregnant while receiving XOSPATA or male patients with pregnant female partners should be apprised of the potential risk to the fetus.

ADVERSE REACTIONS

Clinical Trial Experience

Because 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 safety profile of XOSPATA is based on 319 patients with relapsed or refractory AML treated with gilteritinib 120 mg daily in three clinical trials. The median duration of exposure to XOSPATA was 3.6 months (range 0.1 to 43.4 months).

Fatal adverse reactions occurred in 2% of patients receiving XOSPATA. These included cardiac arrest (1%) and one case each of differentiation syndrome and pancreatitis. The most frequent (≥5%) nonhematological serious adverse reactions reported in patients were fever (13%), dyspnea (9%), renal impairment (8%), transaminase increased (6%) and noninfectious diarrhea (5%).

Of the 319 patients, 91 (29%) required a dose interruption due to an adverse reaction; the most common adverse reactions leading to dose interruption were aspartate aminotransferase increased (6%), alanine aminotransferase increased (6%) and fever (4%). Twenty patients (6%) required a dose reduction due to an adverse reaction. Twenty-two (7%) discontinued XOSPATA treatment permanently due to an adverse reaction.

The most common (>1%) adverse reactions leading to discontinuation were aspartate aminotransferase increased (2%) and alanine aminotransferase increased (2%).

Overall, for the 319 patients, the most frequent (≥10%) all-grade nonhematological adverse reactions reported in patients were transaminase increased (51%), myalgia/arthralgia (50%), fatigue/malaise (44%), fever (41%), mucositis (41%), edema (40%), rash (36%), noninfectious diarrhea (35%), dyspnea (35%), nausea (30%), cough (28%), constipation (28%), eye disorders (25%), headache (24%), dizziness (22%), hypotension (22%), vomiting (21%), renal impairment (21%), abdominal pain (18%), neuropathy (18%), insomnia (15%) and dysgeusia (11%). The most frequent (≥5%) grade ≥3 nonhematological adverse reactions reported in patients were transaminase increased (21%), dyspnea (12%), hypotension (7%), mucositis (7%), myalgia/arthralgia (7%), and fatigue/malaise (6%).

Shifts to grades 3-4 nonhematologic laboratory abnormalities included phosphate decreased (14%), alanine aminotransferase increased (13%), sodium decreased (12%), aspartate aminotransferase increased (10%), calcium decreased (6%), creatine kinase increased (6%), triglycerides increased

(6%), creatinine increased (3%), and alkaline phosphatase increased (2%).

Other clinically significant adverse reactions occurring in ≤10% of patients included: electrocardiogram QT prolonged (9%), hypersensitivity* (8%), pancreatitis* (5%), cardiac failure* (4%), pericardial effusion (4%), acute febrile neutrophilic dermatosis (3%), differentiation syndrome (3%), pericarditis/myocarditis* (2%), large intestine perforation (1%), and posterior reversible encephalopathy syndrome (1%).

*Grouped terms: cardiac failure (cardiac failure, cardiac failure congestive, cardiomegaly, cardiomyopathy, chronic left ventricular failure, and ejection fraction decreased), hypersensitivity (anaphylactic reaction, angioedema, dermatitis allergic, drug hypersensitivity, erythema multiforme, hypersensitivity, and urticaria), pancreatitis (amylase increased, lipase increased, pancreatitis, pancreatitis acute), pericarditis/myocarditis (myocarditis, pericardial hemorrhage, pericardial rub, and pericarditis).

DRUG INTERACTIONS

Combined P-gp and Strong CYP3A Inducers

Concomitant use of XOSPATA with a combined P-gp and strong CYP3A inducer decreases gilteritinib exposure which may decrease XOSPATA efficacy. Avoid concomitant use of XOSPATA with combined P-gp and strong CYP3A inducers.

Strong CYP3A Inhibitors

Concomitant use of XOSPATA with a strong CYP3A inhibitor increases gilteritinib exposure. Consider alternative therapies that are not strong CYP3A inhibitors. If the concomitant use of these inhibitors is considered essential for the care of the patient, monitor patient more frequently for XOSPATA adverse reactions. Interrupt and reduce XOSPATA dosage in patients with serious or life-threatening toxicity.

Drugs that Target 5HT2B Receptor or Sigma Nonspecific Receptor

Concomitant use of gilteritinib may reduce the effects of drugs that target the $5HT_{2B}$ receptor or the sigma nonspecific receptor (e.g., escitalopram, fluoxetine, sertraline). Avoid concomitant use of these drugs with XOSPATA unless their use is considered essential for the care of the patient.

P-gp, BCRP, and OCT1 Substrates

Based on *in vitro* data, gilteritinib is a P-gp, breast cancer resistant protein (BCRP), and organic cation transporter 1 (OCT1) inhibitor. Coadministration of gilteritinib may increase the exposure of P-gp, BCRP, and OCT1 substrates, which may increase the incidence and severity of adverse reactions of these substrates. For P-gp, BCRP, or OCT1 substrates where small concentration changes may lead to serious adverse reactions, decrease the dose or modify the dosing frequency of such substrate and monitor for adverse reactions as recommended in the respective prescribing information.

USE IN SPECIFIC POPULATIONS

Pregnancy

Risk Summary

Based on findings from animal studies and its mechanism of action, XOSPATA can cause fetal harm when administered to a pregnant woman. There are no available data on XOSPATA use in pregnant women to inform a drug-associated risk of adverse developmental outcomes. In animal reproduction studies, administration of gilteritinib to pregnant rats during organogenesis caused adverse developmental outcomes including embryo-fetal lethality, suppressed fetal growth, and teratogenicity at maternal exposures (AUC_{24}) approximately 0.4 times the AUC_{24} in patients receiving the recommended dose. Advise pregnant women of the potential risk to a fetus.

Adverse outcomes in pregnancy occur regardless of the health of the mother or the use of medications. The background risk of major birth defects and miscarriage for the indicated population is unknown. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2%-4% and 15%-20%, respectively.

Data

Animal Data

In an embryo-fetal development study in rats, pregnant animals received oral doses of gilteritinib of 0, 0.3, 3, 10, and 30 mg/kg/day during the period of organogenesis. Maternal findings at 30 mg/kg/day (resulting in exposures approximately 0.4 times the AUC24 in patients receiving the recommended dose) included decreased body weight and food consumption. Administration of gilteritinib at the dose of 30 mg/kg/day also resulted in embryo-fetal death (post implantation loss), decreased fetal body and placental weight, and decreased numbers of ossified sternebrae and sacral and caudal vertebrae, and increased incidence of fetal gross external (anasarca, local edema, exencephaly, cleft lip, cleft palate, short tail, and umbilical hernia), visceral (microphthalmia; atrial and/or ventricular defects; and malformed/absent kidney, and malpositioned adrenal, and ovary), and skeletal (sternoschisis, absent rib, fused rib, fused cervical arch, misaligned cervical vertebra, and absent thoracic vertebra) abnormalities.

Single oral administration of [^{14}C] gilteritinib to pregnant rats resulted in transfer of radioactivity to the fetus similar to that observed in maternal plasma on day 14 of gestation. In addition, distribution profiles of radioactivity in most maternal tissues and the fetus on day 18 of gestation were similar to that on day 14 of gestation.

Lactation

Risk Summary

There are no data on the presence of gilteritinib and/or its metabolites in human milk, the effects on the breastfed child, or the effects on milk production. Following administration of radiolabeled gilteritinib to lactating rats, milk concentrations of radioactivity were higher than radioactivity in maternal plasma at 4 and 24 hours post-dose. In animal studies, gilteritinib and/or its metabolite(s) were distributed to the tissues in infant rats via the milk. Because of the potential for serious adverse reactions in a breastfed child, advise a lactating woman not to breastfeed during treatment with XOSPATA and for 2 months after the last dose.

Females and Males of Reproductive Potential

XOSPATA can cause fetal harm when administered to a pregnant woman.

Pregnancy testing

Pregnancy testing is recommended for females of reproductive potential within seven days prior to initiating XOSPATA treatment.

Contraception

Females

Advise females of reproductive potential to use effective contraception during treatment and for 6 months after the last dose of XOSPATA.

Males

Advise males of reproductive potential to use effective contraception during treatment and for 4 months after the last dose of XOSPATA.

Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

Geriatric Use

Of the 319 patients in clinical studies of XOSPATA, 43% were age 65 years or older, and 13% were 75 years or older. No overall differences in effectiveness or safety were observed between patients age 65 years or older and younger patients.

NONCLINICAL TOXICOLOGY

Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenicity studies have not been performed with gilteritinib. Gilteritinib was not mutagenic in a bacterial mutagenesis (Ames) assay and was not clastogenic in a chromosome aberration test assay in Chinese hamster lung cells. Gilteritinib was positive for the induction of micronuclei in mouse bone marrow cells from 65 mg/kg (195 mg/m^2) the mid dose tested (approximately 2.6 times the recommended human dose of 120 mg). The effect of XOSPATA on human fertility is unknown. Administration of 10 mg/kg/day gilteritinib in the 4-week study in dogs (12 days of dosing) resulted in degeneration and necrosis of germ cells and spermatid giant cell formation in the testis as well as single cell necrosis of the epididymal duct epithelia of the epididymal head.

Animal Toxicology and/or Pharmacology

In the 13-week oral repeated dose toxicity studies in rats and dogs, target organs of toxicity included the eye and kidney.

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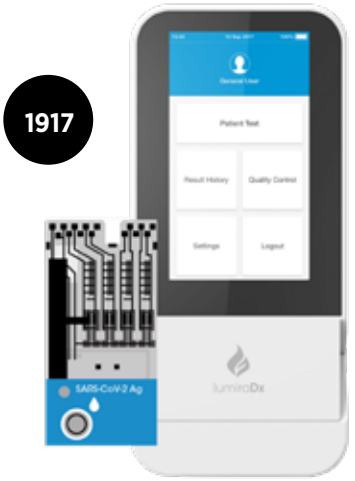
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LumiraDx SARS-CoV-2 Ag test has not been cleared or approved by FDA. The LumiraDx SARS-CoV-2 Ag test has been authorized by FDA under an EUA only for the detection of SARS-CoV-2 nucleocapsid protein. The test has not been authorized for use to detect any other viruses or pathogens. The test is authorized in the United States for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

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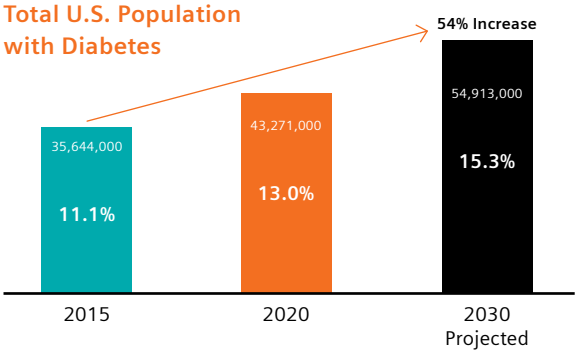


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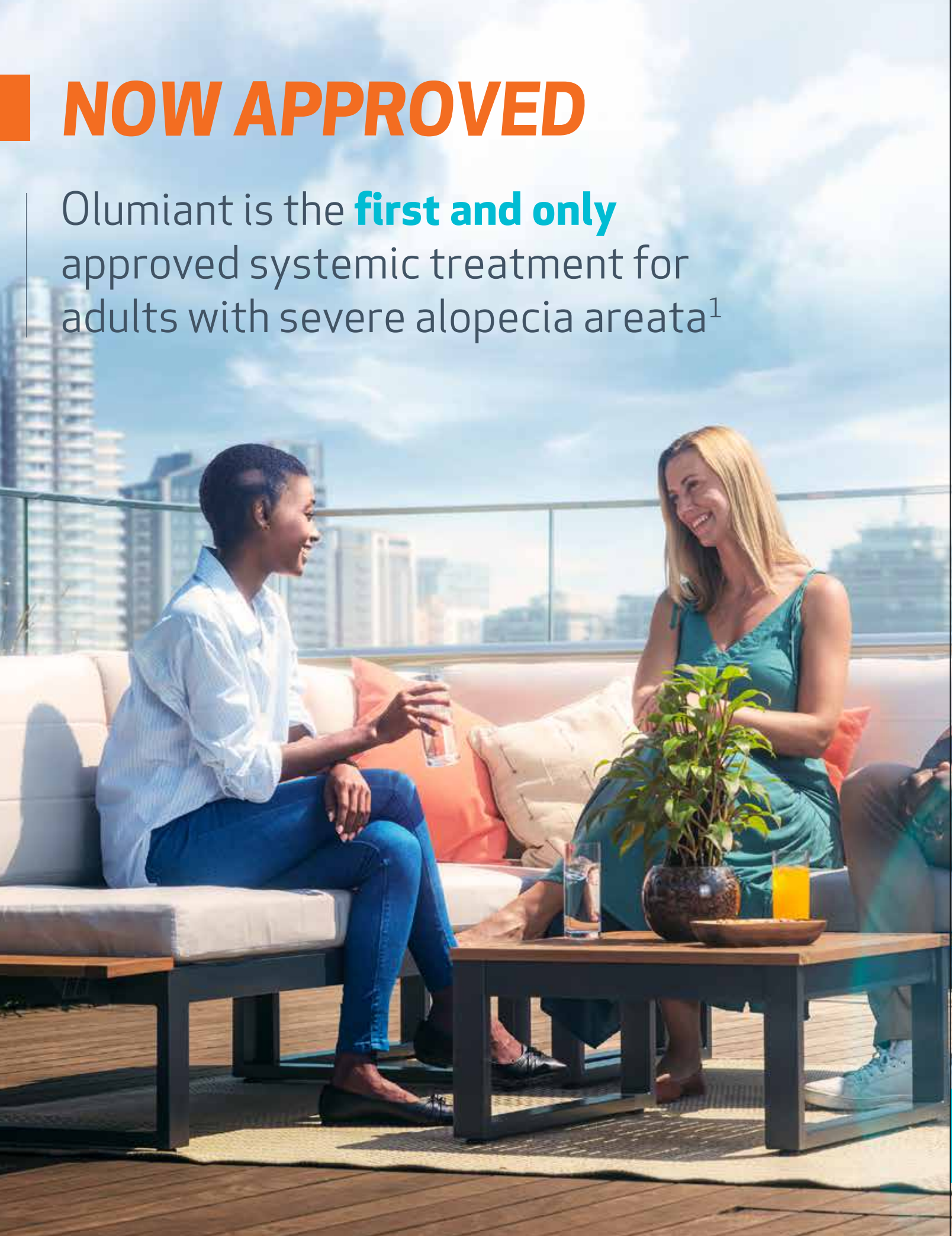
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1. *Rowley, William R et al. "Diabetes 2030: Insights from Yesterday, Today, and Future Trends." Population health management vol. 20,1 (2017): 6-12. doi:10.1089/pop.2015.0181.*

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INDICATION

Olumiant is a Janus kinase (JAK) inhibitor indicated for the treatment of adult patients with severe alopecia areata.

Limitations of Use: Not recommended for use in combination with other JAK inhibitors, biologic immunomodulators, cyclosporine or other potent immunosuppressants.

SELECT IMPORTANT SAFETY INFORMATION: WARNING RELATED TO SERIOUS INFECTIONS, MORTALITY, MALIGNANCY, MAJOR ADVERSE CARDIOVASCULAR EVENTS, AND THROMBOSIS

SERIOUS INFECTIONS: Olumiant-treated patients are at increased risk of serious bacterial, fungal, viral and opportunistic infections leading to hospitalization or death, including tuberculosis (TB). Interrupt treatment with Olumiant if a serious infection occurs until the infection is controlled. Olumiant should not be given to patients with active tuberculosis. Test for latent TB before and during therapy, except for COVID-19; treat latent TB prior to use. Monitor all patients for active TB during treatment, even patients with initial negative, latent TB test.

MORALITY: Higher rate of all-cause mortality, including sudden cardiovascular death was observed with another Janus kinase (JAK) inhibitor vs. tumor necrosis factor (TNF) blockers in rheumatoid arthritis (RA) patients.

MALIGNANCIES: Malignancies have also occurred in patients treated with Olumiant. Higher rate of lymphomas and lung cancers was observed with another JAK inhibitor vs. TNF blockers in RA patients.

MAJOR ADVERSE CARDIOVASCULAR EVENTS (MACE): Higher rate of MACE (defined as cardiovascular death, myocardial infarction, and stroke) was observed with another JAK inhibitor vs. TNF blockers in RA patients.

THROMBOSIS: Thrombosis has occurred in patients treated with Olumiant. Increased incidence of pulmonary embolism, venous and arterial thrombosis was observed with another JAK inhibitor vs. TNF blockers.

Please see the following pages for Important Safety Information, including Boxed Warning about Serious Infections, Mortality, Malignancy, Major Adverse Cardiovascular Events, and Thrombosis, and Brief Summary of Prescribing Information.

Lilly

IMPORTANT SAFETY INFORMATION

WARNING: SERIOUS INFECTIONS, MORTALITY, MALIGNANCY, MAJOR ADVERSE CARDIOVASCULAR EVENTS, AND THROMBOSIS

SERIOUS INFECTIONS

Patients treated with Olumiant are at risk for developing serious infections that may lead to hospitalization or death. Most patients with rheumatoid arthritis (RA) who developed these infections were taking concomitant immunosuppressants such as methotrexate or corticosteroids. If a serious infection develops, interrupt Olumiant until the infection is controlled. Reported infections include:

- **Active tuberculosis (TB), which may present with pulmonary or extrapulmonary disease. Olumiant should not be given to patients with active tuberculosis. Test patients, except those with COVID-19, for latent TB before initiating Olumiant and during therapy. If positive, start treatment for latent infection prior to Olumiant use.**
- **Invasive fungal infections, including candidiasis and pneumocystosis. Patients with invasive fungal infections may present with disseminated, rather than localized, disease.**
- **Bacterial, viral, and other infections due to opportunistic pathogens.**

Carefully consider the risks and benefits of Olumiant prior to initiating therapy in patients with chronic or recurrent infection.

Closely monitor patients for the development of signs and symptoms of infection during and after treatment with Olumiant including the possible development of TB in patients who tested negative for latent TB infection prior to initiating therapy.

The most common serious infections reported with Olumiant included pneumonia, herpes zoster, and urinary tract infection. Among opportunistic infections, tuberculosis, multidermatomal herpes zoster, esophageal candidiasis, pneumocystosis, acute histoplasmosis, cryptococcosis, cytomegalovirus, and BK virus were reported with Olumiant. Some patients have presented with disseminated rather than localized disease, and were often taking concomitant immunosuppressants such as methotrexate or corticosteroids.

Avoid use of Olumiant in patients with an active, serious infection, including localized infections. Consider the risks and benefits of treatment prior to initiating Olumiant in patients: with chronic or recurrent infection; who have been exposed to TB; with a history of a serious or an opportunistic infection; who have resided or traveled in areas of endemic tuberculosis or endemic mycoses; or with underlying conditions that may predispose them to infection.

Consider anti-TB therapy prior to initiation of Olumiant in patients with a history of latent or active TB in whom an adequate course of treatment cannot be confirmed, and for patients with a negative test for latent TB but who have risk factors for TB infection.

Viral reactivation, including cases of herpes virus reactivation (e.g., herpes zoster), were reported in clinical studies with Olumiant. If a patient develops herpes zoster, interrupt Olumiant treatment until the episode resolves. The impact of Olumiant on chronic viral hepatitis reactivation is unknown. Screen for viral hepatitis in accordance with clinical guidelines before initiating Olumiant.

MORTALITY

In a large, randomized, postmarketing safety study in RA patients 50 years of age and older with at least one cardiovascular risk factor comparing another Janus kinase (JAK) inhibitor to tumor necrosis factor (TNF) blockers, a higher rate of all-cause mortality, including sudden cardiovascular death, was observed with the JAK inhibitor.

Consider the benefits and risks for the individual patient prior to initiating or continuing therapy with Olumiant.

MALIGNANCIES

Lymphoma and other malignancies have been observed in patients treated with Olumiant. In RA patients treated with another JAK inhibitor, a higher rate of malignancies (excluding non-melanoma skin cancer [NMSC]) was observed when compared with TNF blockers. Patients who are current or past smokers are at additional increased risk. A higher rate of lymphomas was observed in patients treated with the JAK inhibitor compared to those treated with TNF blockers. A higher rate of lung cancers and an additional increased risk of overall malignancies were observed in current or past smokers treated with the JAK inhibitor compared to those treated with TNF blockers.

Consider the benefits and risks for the individual patient prior to initiating or continuing therapy with Olumiant, particularly in patients with a known malignancy (other than successfully treated NMSC), patients who develop a malignancy, and patients who are current or past smokers.

NMSCs have been reported in patients treated with Olumiant. Periodic skin examination is recommended for patients who are at increased risk for skin cancer.

MAJOR ADVERSE CARDIOVASCULAR EVENTS

In RA patients 50 years of age and older with at least one cardiovascular risk factor treated with another JAK inhibitor, a higher rate of major adverse cardiovascular events (MACE) (defined as cardiovascular death, myocardial infarction [MI], and stroke) was observed when compared with TNF blockers. Patients who are current or past smokers are at additional increased risk. Discontinue Olumiant in patients that have experienced a myocardial infarction or stroke.

Consider the benefits and risks for the individual patient prior to initiating or continuing therapy with Olumiant, particularly in patients who are current or past smokers and patients with other cardiovascular risk factors. Inform patients about the symptoms of serious cardiovascular events and the steps to take if they occur.

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(baricitinib) tablets
4 mg, 2 mg

THROMBOSIS

Thrombosis, including deep venous thrombosis (DVT) and pulmonary embolism (PE), has been observed at an increased incidence in patients treated with Olumiant compared to placebo. In addition, there were cases of arterial thrombosis. Many of these adverse events were serious and some resulted in death. In RA patients 50 years of age and older with at least one cardiovascular risk factor treated with another JAK inhibitor, a higher rate of thrombosis was observed when compared with TNF blockers. Avoid Olumiant in patients at risk. Discontinue Olumiant and promptly evaluate patients with symptoms of thrombosis.

HYPERSENSITIVITY

Reactions such as angioedema, urticaria, and rash that may reflect drug hypersensitivity have been observed in patients receiving Olumiant, including serious reactions. If a serious hypersensitivity reaction occurs, promptly discontinue Olumiant while evaluating the potential causes of the reaction.

GASTROINTESTINAL PERFORATIONS

Gastrointestinal perforations have been reported in Olumiant clinical studies. Monitor Olumiant-treated patients who may be at increased risk for gastrointestinal perforation (e.g., patients with a history of diverticulitis). Promptly evaluate patients who present with new onset abdominal symptoms for early identification of gastrointestinal perforation.

LABORATORY ABNORMALITIES

Neutropenia – Olumiant treatment was associated with an increased incidence of neutropenia (absolute neutrophil count [ANC] <1000 cells/mm^3) compared to placebo. Evaluate at baseline and thereafter according to routine patient management. In patients with RA or alopecia areata (AA), avoid initiation or interrupt Olumiant treatment in patients with an ANC <1000 cells/mm^3.

Lymphopenia – Absolute lymphocyte count (ALC) <500 cells/mm^3 were reported in Olumiant clinical trials. Lymphocyte counts less than the lower limit of normal were associated with infection in patients treated with Olumiant, but not placebo. Evaluate at baseline and thereafter according to routine patient management. In patients with RA or AA, avoid initiation or interrupt Olumiant treatment in patients with an ALC <500 cells/mm^3.

Anemia – Decreases in hemoglobin levels to <8 g/dL were reported in Olumiant clinical trials. Evaluate at baseline and thereafter according to routine patient management. In patients with RA or AA, avoid initiation or interrupt Olumiant treatment in patients with hemoglobin <8 g/dL.

Liver Enzyme Elevations – Olumiant treatment was associated with increased incidence of liver enzyme elevation compared to placebo. Increases of alanine transaminase (ALT) ≥5x upper limit of normal (ULN) and increases of aspartate transaminase (AST) ≥10x ULN were observed in patients in Olumiant clinical trials

Evaluate at baseline and thereafter according to routine patient management. Promptly investigate the cause of liver enzyme elevation to identify potential cases of drug-induced liver injury. If increases in ALT or AST are observed and drug-induced liver injury is suspected, interrupt Olumiant until this diagnosis is excluded.

Lipid Elevations – Treatment with Olumiant was associated with increases in lipid parameters, including total cholesterol, low-density lipoprotein cholesterol, and high-density lipoprotein cholesterol. Assess lipid parameters approximately 12 weeks following Olumiant initiation in patients with RA or AA. Manage patients according to clinical guidelines for the management of hyperlipidemia.

VACCINATIONS

Avoid use of live vaccines with Olumiant. Update immunizations in patients with RA or AA prior to initiating Olumiant therapy in agreement with current immunization guidelines.

ADVERSE REACTIONS

In RA trials, the most common adverse reactions (≥1%) reported with Olumiant were: upper respiratory tract infections, nausea, herpes simplex, and herpes zoster.

In AA trials, the most common adverse reactions (≥1%) reported with Olumiant were: upper respiratory tract infections, headache, acne, hyperlipidemia, creatine phosphokinase increase, urinary tract infection, liver enzyme elevations, folliculitis, fatigue, lower respiratory tract infections, nausea, genital Candida infections, anemia, neutropenia, abdominal pain, herpes zoster, and weight increase.

PREGNANCY AND LACTATION

Based on animal studies, Olumiant may cause fetal harm when administered during pregnancy. Advise pregnant women and women of reproductive potential of the potential risk to a fetus. Consider pregnancy planning and prevention for women of reproductive potential. Advise women not to breastfeed during treatment with Olumiant and for 4 days after the last dose.

HEPATIC AND RENAL IMPAIRMENT

Olumiant is not recommended in patients with RA or AA and severe hepatic impairment or severe renal impairment (estimated glomerular filtration rate [eGFR] <30 mL/min/1.73m^2).

Please see the following pages for Brief Summary of Prescribing Information, including Boxed Warning about Serious Infections, Mortality, Malignancy, Major Adverse Cardiovascular Events, and Thrombosis.

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Reference: 1. Olumiant. Prescribing Information. Lilly USA, LLC.

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Lilly

OLUMIANT® (baricitinib) TABLETS BRIEF SUMMARY OF PRESCRIBING INFORMATION

Consult the package insert for complete prescribing information.

INDICATIONS AND USAGE

Rheumatoid Arthritis: Olumiant is indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more tumor necrosis factor (TNF) blockers.

Limitations of Use: Not recommended for use in combination with other Janus kinase (JAK) inhibitors, biologic disease-modifying antirheumatic drugs (DMARDs), or with potent immunosuppressants such as azathioprine and cyclosporine.

Coronavirus Disease 2019 (COVID-19): Olumiant is indicated for the treatment of COVID-19 in hospitalized adults requiring supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO).

Alopecia Areata: Olumiant is indicated for the treatment of adult patients with severe alopecia areata.

Limitations of Use: Not recommended for use in combination with other JAK inhibitors, biologic immunomodulators, cyclosporine or other potent immunosuppressants.

WARNING: SERIOUS INFECTIONS, MORTALITY, MALIGNANCY, MAJOR ADVERSE CARDIOVASCULAR EVENTS (MACE), and THROMBOSIS

SERIOUS INFECTIONS

Patients treated with Olumiant are at risk for developing serious infections that may lead to hospitalization or death. Most patients with rheumatoid arthritis (RA) who developed these infections were taking concomitant immunosuppressants such as methotrexate or corticosteroids.

If a serious infection develops, interrupt Olumiant until the infection is controlled.

Reported infections include:

- **Active tuberculosis, which may present with pulmonary or extrapulmonary disease. Olumiant should not be given to patients with active tuberculosis. Patients, except those with COVID-19, should be tested for latent tuberculosis before initiating Olumiant and during therapy. If positive, start treatment for latent infection prior to Olumiant use.**
- **Invasive fungal infections, including candidiasis and pneumocystosis. Patients with invasive fungal infections may present with disseminated, rather than localized, disease.**
- **Bacterial, viral, and other infections due to opportunistic pathogens.**

The risks and benefits of treatment with Olumiant should be carefully considered prior to initiating therapy in patients with chronic or recurrent infection.

Patients should be closely monitored for the development of signs and symptoms of infection during and after treatment with Olumiant including the possible development of tuberculosis in patients who tested negative for latent tuberculosis infection prior to initiating therapy.

MORTALITY

In a large, randomized, postmarketing safety study in RA patients 50 years of age and older with at least one cardiovascular risk factor comparing another JAK inhibitor to tumor necrosis factor (TNF) blockers, a higher rate of all-cause mortality, including sudden cardiovascular death, was observed with the JAK inhibitor.

MALIGNANCIES

Lymphoma and other malignancies have been observed in patients treated with Olumiant. In RA patients treated with another JAK inhibitor, a higher rate of malignancies (excluding non-melanoma skin cancer [NMSC]) was observed when compared with TNF blockers. Patients who are current or past smokers are at additional increased risk.

MAJOR ADVERSE CARDIOVASCULAR EVENTS

In RA patients 50 years of age and older with at least one cardiovascular risk factor treated with another JAK inhibitor, a higher rate of major adverse cardiovascular events (MACE) (defined as cardiovascular death, myocardial infarction, and stroke) was observed when compared with TNF blockers. Patients who are current or past smokers are at additional increased risk. Discontinue Olumiant in patients that have experienced a myocardial infarction or stroke.

THROMBOSIS

Thrombosis, including deep venous thrombosis and pulmonary embolism, has been observed at an increased incidence in patients treated with Olumiant compared to placebo. In addition, there were cases of arterial thrombosis. Many of these adverse events were serious and some resulted in death. In RA patients 50 years of age and older with at least one cardiovascular risk factor treated with another JAK inhibitor, a higher rate of thrombosis was observed when compared with TNF blockers. Avoid Olumiant in patients at risk. Patients with symptoms of thrombosis should discontinue Olumiant and be promptly evaluated.

WARNINGS AND PRECAUTIONS

Serious Infections—Serious and sometimes fatal infections due to bacterial, mycobacterial, invasive fungal, viral, or other opportunistic pathogens have been reported in patients with rheumatoid arthritis receiving Olumiant. The most common serious infections reported with Olumiant included pneumonia, herpes zoster, and urinary tract infection. Among opportunistic infections, tuberculosis, multidermatomal herpes zoster, esophageal candidiasis, pneumocystosis, acute histoplasmosis, cryptococcosis, cytomegalovirus, and BK virus were reported with Olumiant. Some patients have presented with disseminated rather than localized disease, and were often taking concomitant immunosuppressants such as methotrexate or corticosteroids.

Avoid use of Olumiant in patients with an active, serious infection, including localized infections. Consider the risks and benefits of treatment prior to initiating Olumiant in patients:

- with chronic or recurrent infection
- who have been exposed to tuberculosis
- with a history of a serious or an opportunistic infection
- who have resided or traveled in areas of endemic tuberculosis or endemic mycoses; or
- with underlying conditions that may predispose them to infection.

In patients with rheumatoid arthritis or alopecia areata, closely monitor for the development of signs and symptoms of infection during and after treatment with Olumiant. Interrupt Olumiant in patients with rheumatoid arthritis or alopecia areata, if the patient develops a serious infection, an opportunistic infection, or sepsis. A patient who develops a new infection during treatment with Olumiant should undergo prompt and complete diagnostic testing appropriate for an immunocompromised patient; appropriate antimicrobial therapy should be initiated, the patient should be closely monitored, and Olumiant should be interrupted if the patient is not responding to therapy. Do not resume Olumiant until the infection is controlled.

In patients with COVID-19, monitor for signs and symptoms of new infections during and after treatment with Olumiant. There is limited information regarding the use of Olumiant in patients with COVID-19 and concomitant active serious infections. The risks and benefits of treatment with Olumiant in COVID-19 patients with other concurrent infections should be considered.

Tuberculosis—Evaluate patients for active infection prior to administration of Olumiant. Olumiant should not be given to patients with active tuberculosis (TB).

Test patients with rheumatoid arthritis or alopecia areata for latent tuberculosis. Patients with rheumatoid arthritis or alopecia areata and latent TB should be treated with standard antimycobacterial therapy before initiating Olumiant. Consider anti-TB therapy prior to initiation of Olumiant in patients with a history of latent or active TB in whom an adequate course of treatment cannot be confirmed, and for patients with a negative test for latent TB but who have risk factors for TB infection. Consultation with a physician with expertise in the treatment of TB is recommended to aid in the decision about whether initiating anti-TB therapy is appropriate for an individual patient.

During Olumiant use, monitor patients for the development of signs and symptoms of TB, including patients who tested negative for latent TB infection prior to initiating therapy.

Viral Reactivation**—**Viral reactivation, including cases of herpes virus reactivation (e.g., herpes zoster), were reported in clinical studies with Olumiant. If a patient develops herpes zoster, interrupt Olumiant treatment until the episode resolves.

The impact of Olumiant on chronic viral hepatitis reactivation is unknown. Patients with evidence of active hepatitis B or C infection were excluded from clinical trials. In clinical trials in patients with rheumatoid arthritis or alopecia areata, patients who were positive for hepatitis C antibody but negative for hepatitis C virus RNA were permitted to enroll. Patients with positive hepatitis B surface antibody and hepatitis B core antibody, without hepatitis B surface antigen, were permitted to enroll; such patients should be monitored for expression of hepatitis B virus (HBV) DNA. Should HBV DNA be detected, consult with a hepatologist. Perform screening for viral hepatitis in accordance with clinical guidelines before starting therapy with Olumiant.

Mortality—In a large, randomized, postmarketing safety study of another JAK inhibitor in RA patients 50 years of age and older with at least one cardiovascular risk factor, a higher rate of all-cause mortality, including sudden cardiovascular death, was observed in patients treated with the JAK inhibitor compared with TNF blockers. Consider the benefits and risks for the individual patient prior to initiating or continuing therapy with Olumiant.

Malignancy and Lymphoproliferative Disorders— Malignancies were observed in clinical studies of Olumiant.

In a large, randomized, postmarketing safety study of another JAK inhibitor in RA patients, a higher rate of malignancies (excluding non-melanoma skin cancer [NMSC]) was observed in patients treated with the JAK inhibitor compared to those treated with TNF blockers. A higher rate of lymphomas was observed in patients treated with the JAK inhibitor compared to those treated with TNF blockers. A higher rate of lung cancers was observed in current or past smokers treated with the JAK inhibitor compared to those treated with TNF blockers. In this study, current or past smokers had an additional increased risk of overall malignancies.

Consider the benefits and risks for the individual patient prior to initiating or continuing therapy with Olumiant, particularly in patients with a known malignancy (other than successfully treated NMSC), patients who develop a malignancy, and patients who are current or past smokers.

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Non-melanoma skin cancers—NMSCs have been reported in patients treated with Olumiant. Periodic skin examination is recommended for patients who are at increased risk for skin cancer.

Major Adverse Cardiovascular Events—In a large, randomized, postmarketing safety study of another JAK inhibitor in RA patients 50 years of age and older with at least one cardiovascular risk factor, a higher rate of major adverse cardiovascular events (MACE) defined as cardiovascular death, non-fatal myocardial infarction (MI), and non-fatal stroke was observed with the JAK inhibitor compared to those treated with TNF blockers. Patients who are current or past smokers are at additional increased risk.

Consider the benefits and risks for the individual patient prior to initiating or continuing therapy with Olumiant, particularly in patients who are current or past smokers and patients with other cardiovascular risk factors. Patients should be informed about the symptoms of serious cardiovascular events and the steps to take if they occur. Discontinue Olumiant in patients that have experienced a myocardial infarction or stroke.

Thrombosis—Thrombosis, including deep venous thrombosis (DVT) and pulmonary embolism (PE), has been observed at an increased incidence in patients treated with Olumiant compared to placebo. In addition, arterial thrombosis events in the extremities have been reported in clinical studies with Olumiant. Many of these adverse events were serious and some resulted in death. There was no clear relationship between platelet count elevations and thrombotic events. In a large, randomized, postmarketing safety study of another JAK inhibitor in RA patients 50 years of age and older with at least one cardiovascular risk factor, higher rates of overall thrombosis, DVT, and PE were observed compared to those treated with TNF blockers.

If clinical features of DVT/PE or arterial thrombosis occur, patients should discontinue Olumiant and be evaluated promptly and treated appropriately. Avoid Olumiant in patients that may be at increased risk of thrombosis.

Hypersensitivity—Reactions such as angioedema, urticaria, and rash that may reflect drug hypersensitivity have been observed in patients receiving Olumiant, including serious reactions. If a serious hypersensitivity reaction occurs, promptly discontinue Olumiant while evaluating the potential causes of the reaction.

Gastrointestinal Perforations—Gastrointestinal perforations have been reported in clinical studies with Olumiant.

Monitor Olumiant-treated patients who may be at increased risk for gastrointestinal perforation (e.g., patients with a history of diverticulitis). Evaluate promptly patients presenting with new onset abdominal symptoms for early identification of gastrointestinal perforation.

Laboratory Abnormalities

Neutropenia—Treatment with Olumiant was associated with an increased incidence of neutropenia (absolute neutrophil count [ANC] less than 1000 cells/mm^3) compared to placebo.

In patients with rheumatoid arthritis or alopecia areata, avoid initiation or interrupt Olumiant treatment in patients with an ANC less than 1000 cells/mm^3.

In patients with COVID-19, there is limited information regarding use of Olumiant in patients with ANC less than 1000 cells/mm^3. Avoid initiation or interrupt Olumiant treatment in patients with COVID-19 and an ANC less than 500 cells/mm^3.

Evaluate at baseline and thereafter according to routine patient management. Adjust dosing based on ANC.

Lymphopenia—Absolute lymphocyte count (ALC) less than 500 cells/mm^3 were reported in Olumiant clinical trials. Lymphocyte counts less than the lower limit of normal were associated with infection in patients treated with Olumiant, but not placebo.

In patients with rheumatoid arthritis or alopecia areata, avoid initiation or interrupt Olumiant treatment in patients with an ALC less than 500 cells/mm^3.

In patients with COVID-19, there is limited information regarding use of Olumiant in patients with ALC less than 200 cells/mm^3. Avoid initiation or interrupt Olumiant treatment in patients with COVID-19 and an ALC less than 200 cells/mm^3.

Evaluate at baseline and thereafter according to routine patient management. Adjust dosing based on ALC.

Anemia—Decreases in hemoglobin levels to less than 8 g/dL were reported in Olumiant clinical trials. In patients with rheumatoid arthritis or alopecia areata, avoid initiation or interrupt Olumiant treatment in patients with hemoglobin less than 8 g/dL. Evaluate at baseline and thereafter according to routine patient management. Adjust dosing based on hemoglobin levels.

In patients with COVID-19, there is limited information regarding use of Olumiant in patients with hemoglobin less than 8 g/dL.

Liver Enzyme Elevations—Treatment with Olumiant was associated with increased incidence of liver enzyme elevation compared to placebo. Increases of ALT ≥5 times upper limit of normal (ULN) and increases of AST ≥10 times ULN were observed in patients in Olumiant clinical trials. Evaluate at baseline and thereafter according to routine patient management. Prompt investigation of the cause of liver enzyme elevation is recommended to identify potential cases of drug-induced liver injury. If increases in ALT or AST are observed and drug-induced liver injury is suspected, interrupt Olumiant until this diagnosis is excluded.

Lipid Elevations—Treatment with Olumiant was associated with increases in lipid parameters, including total cholesterol, low-density lipoprotein (LDL) cholesterol, and high-density lipoprotein (HDL) cholesterol. Assessment of lipid parameters should be performed approximately 12 weeks following Olumiant initiation in patients with rheumatoid arthritis or alopecia areata. Manage patients according to clinical guidelines for the management of hyperlipidemia.

Vaccinations—Avoid use of live vaccines with Olumiant. Update immunizations in patients with rheumatoid arthritis or alopecia areata prior to initiating Olumiant therapy in agreement with current immunization guidelines.

ADVERSE REACTIONS

The following clinically significant adverse reactions are described elsewhere in the labeling *(see Warnings and Precautions)*: Serious Infections; Mortality; Malignancy and Lymphoproliferative Disorders; Major Adverse Cardiovascular Events; Thrombosis; Hypersensitivity; Gastrointestinal Perforations; Laboratory Abnormalities.

Clinical Trials Experience—Because clinical studies are conducted under widely varying conditions, adverse reaction rates observed in the clinical studies of a drug cannot be directly compared to rates in the clinical studies of another drug and may not predict the rates observed in a broader patient population in clinical practice.

Adverse Reactions in Patients with Rheumatoid Arthritis—The safety of Olumiant was evaluated in six randomized, double-blind, placebo-controlled studies (three Phase 2, three Phase 3) and a long-term extension study in patients with moderately to severely active RA. Patients were randomized to placebo (1070 patients), Olumiant 2 mg (479 patients), or baricitinib 4 mg (997 patients).

Patients could be switched to baricitinib 4 mg from placebo or Olumiant 2 mg from as early as Week 12 depending on the study design. All patients initially randomized to placebo were switched to baricitinib 4 mg by Week 24.

During the 16-week treatment period, adverse events leading to discontinuation of treatment were reported by 35 patients (11.4 per 100 patient-years) treated with placebo, 17 patients (12.1 per 100 patient-years) with Olumiant 2 mg, and 40 patients (13.4 per 100 patient-years) treated with baricitinib 4 mg.

During 0 to 52-week exposure, adverse events leading to discontinuation of treatment were reported by 31 patients (9.2 per 100 patient-years) with Olumiant 2 mg, and 92 patients (10.2 per 100 patient-years) treated with baricitinib 4 mg.

Overall Infections—During the 16-week treatment period, infections were reported by 253 patients (82.1 per 100 patient-years) treated with placebo, 139 patients (99.1 per 100 patient-years) treated with Olumiant 2 mg, and 298 patients (100.1 per 100 patient-years) treated with baricitinib 4 mg.

During 0 to 52-week exposure, infections were reported by 200 patients (59.6 per 100 patients-years) treated with Olumiant 2 mg, and 500 patients (55.3 per 100 patient-years) treated with baricitinib 4 mg.

In the 0 to 52-week exposure population, the most commonly reported infections with Olumiant were viral upper respiratory tract infection, upper respiratory tract infection, urinary tract infection, and bronchitis.

Serious Infections—During the 16-week treatment period, serious infections were reported in 13 patients (4.2 per 100 patient-years) treated with placebo, 5 patients (3.6 per 100 patient-years) treated with Olumiant 2 mg, and 11 patients (3.7 per 100 patient-years) treated with baricitinib 4 mg.

During 0 to 52-week exposure, serious infections were reported in 14 patients (4.2 per 100 patient-years) treated with Olumiant 2 mg and 32 patients (3.5 per 100 patient-years) treated with baricitinib 4 mg.

In the 0 to 52 week exposure population, the most commonly reported serious infections with Olumiant were pneumonia, herpes zoster, and urinary tract infection.

Tuberculosis—During the 16-week treatment period, no events of tuberculosis were reported.

During 0 to 52-week exposure, events of tuberculosis were reported in 0 patients treated with Olumiant 2 mg and 1 patient (0.1 per 100 patient-years) treated with baricitinib 4 mg.

Cases of disseminated tuberculosis were also reported.

Opportunistic Infections (excluding tuberculosis)—During the 16-week treatment period, opportunistic infections were reported in 2 patients (0.6 per 100 patient-years) treated with placebo, 0 patients treated with Olumiant 2 mg and 2 patients (0.7 per 100 patient-years) treated with baricitinib 4 mg.

During 0 to 52-week exposure, opportunistic infections were reported in 1 patient (0.3 per 100 patient-years) treated with Olumiant 2 mg and 5 patients (0.6 per 100 patient-years) treated with baricitinib 4 mg.

Malignancies—During the 16-week treatment period, malignancies excluding non-melanoma skin cancers (NMSC) were reported in 0 patients treated with placebo, 1 patient (0.7 per 100 patient-years) treated with Olumiant 2 mg, and 1 patient (0.3 per 100 patient-years) treated with baricitinib 4 mg.

During the 0 to 52-week treatment period, malignancies excluding NMSC were reported in 2 patients (0.6 per 100 patient-years) treated with Olumiant 2 mg and 6 patients (0.7 per 100 patient-years) treated with baricitinib 4 mg.

Thrombosis

Venous Thrombosis—During the 16-week treatment period, venous thromboses (deep vein thrombosis or pulmonary embolism) were reported in 0 patients treated with placebo, 0 patients treated with Olumiant 2 mg, and 5 patients (1.7 per 100 patient-years) treated with baricitinib 4 mg. During the 0 to 52-week treatment period, venous thromboses were reported in 2 patients (0.6 per 100 patient-years) treated with Olumiant 2 mg and 7 patients (0.8 per 100 patient-years) treated with baricitinib 4 mg.

Arterial Thrombosis—During the 16-week treatment period, arterial thromboses were reported in 1 patient treated with placebo (0.3 per 100 patient-years), 2 patients (1.4 per 100 patient-years) treated with Olumiant 2 mg, and 2 patients (0.7 per 100 patient-years) treated with baricitinib 4 mg. During the 0 to 52-week treatment period, arterial thromboses were reported in 3 patients (0.9 per 100 patient-years) treated with Olumiant 2 mg and 3 patients (0.3 per 100 patient-years) treated with baricitinib 4 mg.

Laboratory Abnormalities

Neutropenia—During the 16-week treatment period, neutrophil counts below 1000 cells/mm^3 occurred in 0% of patients treated with placebo, 0.6% of patients treated with Olumiant 2 mg, and 0.3% of patients treated with baricitinib 4 mg. There were no neutrophil counts below 500 cells/mm^3 observed in any treatment group.

Platelet Elevations—During the 16-week treatment period, increases in platelet counts above 600,000 cells/mm^3 occurred in 1.1% of patients treated with placebo, 1.1% of patients treated with Olumiant 2 mg, and 2.0% of patients treated with baricitinib 4 mg. Mean platelet count increased by 3000 cells/mm^3 at 16 weeks in patients treated with placebo, by 15,000 cells/mm^3 at 16 weeks in patients treated with Olumiant 2 mg and by 23,000 cells/mm^3 in patients treated with baricitinib 4 mg.

Liver Enzyme Elevations—Events of increases in liver enzymes ≥3 times the ULN were observed in patients treated with Olumiant.

- During the 16-week treatment period, ALT elevations ≥3 times the ULN occurred in 1.0% of patients treated with placebo, 1.7% of patients treated with Olumiant 2 mg, and 1.4% of patients treated with baricitinib 4 mg.
- During the 16-week treatment period, AST elevations ≥3 times the ULN occurred in 0.8% of patients treated with placebo, 1.3% of patients treated with Olumiant 2 mg, and 0.8% of patients treated with baricitinib 4 mg.
- In a phase 3 study of DMARD naive patients, during the 24-week treatment period, ALT and AST elevations ≥3 times the ULN occurred in 1.9% and 0% of patients treated with methotrexate monotherapy, 1.9% and 1.3% of patients treated with baricitinib 4 mg monotherapy, and 4.7% and 1.9% of patients treated with baricitinib 4 mg plus methotrexate.

Lipid Elevations—In controlled clinical trials, Olumiant treatment was associated with dose-related increases in lipid parameters, including total cholesterol, triglycerides, LDL cholesterol, and HDL cholesterol. Elevations were observed at 12 weeks and remained stable thereafter. During the 12-week treatment period, changes in lipid parameters are summarized below:

- Mean LDL cholesterol increased by 8 mg/dL in patients treated with Olumiant 2 mg and by 14 mg/dL in patients treated with baricitinib 4 mg.
- Mean HDL cholesterol increased by 7 mg/dL in patients treated with Olumiant 2 mg and by 9 mg/dL in patients treated with baricitinib 4 mg.
- The mean LDL/HDL ratio remained stable.
- Mean triglycerides increased by 7 mg/dL in patients treated with Olumiant 2 mg and by 15 mg/dL in patients treated with baricitinib 4mg.

Creatine Phosphokinase (CPK)—Olumiant treatment was associated with increases in CPK within one week of starting Olumiant and plateauing after 8 to 12 weeks. At 16 weeks, the mean change in CPK for Olumiant 2 mg and baricitinib 4 mg was 37 IU/L and 52 IU/L, respectively.

Creatinine—In controlled clinical trials, dose-related increases in serum creatinine were observed with Olumiant treatment. At 52 weeks, the mean increase in serum creatinine was less than 0.1 mg/dL with baricitinib 4 mg. The clinical significance of the observed serum creatinine increases is unknown.

Other Adverse Reactions—Other adverse reactions are summarized in the following table.

Adverse Reactions Occurring in Greater Than or Equal to 1% of Olumiant 2 mg and Baricitinib 4 mg Treated Patients in Placebo-Controlled Trials for Rheumatoid Arthritis

	Weeks 0-16		
	Placebo n=1070 (%)	Olumiant 2 mg n=479 (%)	Baricitinib 4 mg n=997 (%)
Upper respiratory tract infections[a]	11.7	16.3	14.7
Nausea	1.6	2.7	2.8
Herpes simplex[b]	0.7	0.8	1.8
Herpes zoster	0.4	1.0	1.4

[a] Includes acute sinusitis, acute tonsillitis, chronic tonsillitis, epiglottitis, laryngitis, nasopharyngitis, oropharyngeal pain, pharyngitis, pharyngotonsillitis, rhinitis, sinobronchitis, sinusitis, tonsillitis, tracheitis, and upper respiratory tract infection.

[b] Includes eczema herpeticum, genital herpes, herpes simplex, ophthalmic herpes simplex, and oral herpes.

Additional adverse drug reactions occurring in fewer than 1% of patients: acne.

Adverse Reactions in Patients with COVID-19—The safety of Olumiant was evaluated in two randomized, double-blind, placebo-controlled clinical trials of hospitalized adults with COVID-19 for up to 29 days, in which 1307 patients received at least one dose of Olumiant 4 mg once daily, and 1310 patients received placebo, for up to 14 days or until hospital discharge, whichever occurred first. In these studies, prophylaxis for venous thromboembolic event (VTEs) was recommended or required for all patients unless a major contraindication was noted.

Overall, the safety profile observed in patients with COVID-19 treated with Olumiant was consistent with the safety profile in patients with rheumatoid arthritis.

Overall Infections—During the first 29 days of the randomized clinical trials, infections were reported in 194 patients (14.8%) treated with Olumiant 4 mg and by 219 patients (16.7%) treated with placebo. The most commonly reported infection with Olumiant was pneumonia (3.1%).

Serious Infections—During the first 29 days of the randomized clinical trials, serious infections were reported in 98 patients (7.5%) treated with Olumiant 4 mg and 120 patients (9.2%) treated with placebo. The most commonly reported serious infections with Olumiant were COVID-19 pneumonia (2.1%) and septic shock (2.1%).

Opportunistic Infections—During the first 29 days of the randomized clinical trials, opportunistic infections were reported in 12 patients (0.9%) treated with Olumiant 4 mg and 14 patients (1.1%) treated with placebo. Tuberculosis was reported in 1 patient (0.1%) treated with Olumiant 4 mg and 0 patients treated with placebo.

Venous Thrombosis Events—During the first 29 days of the randomized clinical trials, pulmonary embolism was reported in 20 patients (1.5%) treated with Olumiant 4 mg and 11 patients (0.8%) treated with placebo. Deep vein thrombosis was reported in 20 patients (1.5%) treated with Olumiant 4 mg and 18 patients (1.4%) treated with placebo.

Adverse drug reactions in greater than or equal to 1% of patients in trials for COVID-19 are summarized in the following table.

Adverse Reactions That Occurred in Greater Than or Equal to 1% of Patients Treated with Olumiant 4 mg During the First 29 Days in Placebo-Controlled Trials for COVID-19

	Placebo N=1310 n (%)	Olumiant 4 mg N=1307 n (%)
ALT ≥3 x ULN[a]	201(16.0)	230 (18.1)
AST ≥3 x ULN[a]	117 (9.4)	149 (11.8)
Thrombocytosis >600,000 cells/mm^3[a]	34 (4.6)	59 (7.9)
Creatine phosphokinase (CPK) >5 x ULN[a, b]	38 (4.7)	36 (4.5)
Neutropenia <1000 cells/mm^3[a]	22 (1.8)	26 (2.2)
Deep vein thrombosis	18 (1.4)	20 (1.5)
Pulmonary embolism	11 (0.8)	20 (1.5)
Urinary tract infection	13 (1.0)	19 (1.5)

[a] As assessed by measured values within the clinical trial database. Frequencies are based on shifts from pre-treatment to post-treatment (with number at risk as the denominator), except for ALT and AST for which frequencies are based on observed elevation during treatment.

[b] Creatine phosphokinase frequencies presented in the table were available for a single trial (COVID II) in patients with COVID-19 and do not represent integrated data.

Adverse Reactions in Patients with Alopecia Areata—The safety of Olumiant was evaluated in two placebo-controlled studies in patients with severe alopecia areata (one phase 2/3 study, and one phase 3 study). Patients were randomized to placebo (371 patients), Olumiant 2 mg (365 patients), or Olumiant 4 mg (540 patients). Of these, a total of 845 patients were treated with Olumiant for at least 1 year.

The following table summarizes adverse reactions that occurred at a frequency of at least 1% in patients treated with Olumiant 2 mg once daily or Olumiant 4 mg once daily and more frequently than in patients treated with placebo during the 36-week placebo-controlled period of the alopecia areata clinical trials.

Adverse Reactions That Occurred in ≥1% of Patients Treated with Olumiant 2 mg or Olumiant 4 mg in Alopecia Areata Trials

	Weeks 0-36		
	Placebo n=371 (%)[a]	Olumiant 2 mg n=365 (%)[a]	Olumiant 4 mg n=540 (%)[a]
Upper respiratory tract infections (URTI)[b]	19.9	18.4	21.3
Headache	5.4	5.5	6.6
Acne[c]	2.2	5.8	5.9
Hyperlipidemia[d]	3.0	3.6	5.9
Blood creatine phosphokinase increased	1.3	0.8	4.3
Urinary tract infections (UTI)[e]	2.2	3.8	3.7

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Adverse Reactions That Occurred in ≥1% of Patients Treated with Olumiant 2 mg or Olumiant 4 mg in Alopecia Areata Trials (Cont.)

	Weeks 0-36		
	Placebo n=371 (%)[a]	Olumiant 2 mg n=365 (%)[a]	Olumiant 4 mg n=540 (%)[a]
Liver enzyme elevations[f]	2.4	1.1	3.0
Folliculitis[g]	0.8	1.4	2.2
Fatigue	1.1	0.8	2.2
Lower respiratory tract infections (LRTI)[h]	0.8	2.2	2.0
Nausea	1.6	2.7	2.0
Genital Candida infections[i]	0.3	2.2	1.3
Anemia	0.3	0.3	1.3
Neutropenia[j]	0.8	0.3	1.3
Abdominal pain[k]	2.2	3.8	0.9
Herpes zoster	0.5	1.4	0.9
Weight increased	0.3	1.6	0.9

[a] %-study size adjusted percentages.

[b] URTI includes: acute sinusitis, influenza, laryngitis, nasopharyngitis, oropharyngeal pain, pharyngitis, pharyngotonsillitis, rhinitis, sinusitis, tonsillitis, upper respiratory tract infection, viral upper respiratory tract infection, viral sinusitis, viral pharyngitis, respiratory tract infection viral, rhinovirus infection and adenoiditis

[c] Acne includes: acne and dermatitis acneiform.

[d] Hyperlipidemia includes: hyperlipidaemia, hypercholesterolaemia, hypertriglyceridaemia, dyslipidaemia, lipids increased, low density lipoprotein increased, blood cholesterol increased, and blood triglycerides increased.

[e] UTI includes: cystitis, urinary tract infection, white blood cells urine positive, urinary tract infection bacterial, and pyelonephritis.

[f] Liver enzyme elevations includes: transaminases increased, aspartate aminotransferase increased, alanine aminotransferase increased, hepatic enzyme increased, gamma-glutamyl transferase increased, and hepatic function abnormal.

[g] Folliculitis was most commonly localized in the scalp region associated with hair regrowth.

[h] LRTI includes: bronchitis, bronchiolitis, lower respiratory tract infection, pneumonia, COVID-19 pneumonia, and respiratory tract infection.

[i] Genital Candida infections includes: vulvovaginal candidiasis, vulvovaginal mycotic infection, and genital infection fungal.

[j] Neutropenia includes: neutropenia and neutrophil count decreased.

[k] Abdominal pain includes: abdominal pain, abdominal pain lower, abdominal pain upper, and abdominal discomfort.

In patients treated with any dose of baricitinib, adverse reactions that occurred in fewer than 1% of patients include arterial thrombosis, B cell lymphoma, lymphopenia, and fungal skin infections.

Additional adverse reactions observed after Week 52: venous thromboembolic events (VTE), including deep venous thrombosis (DVT) and pulmonary embolism (PE), and malignancy including non-melanoma skin cancer.

Overall, the adverse reactions observed in patients with alopecia areata treated with Olumiant were consistent with the adverse reactions in patients with rheumatoid arthritis.

Postmarketing Experience—The following adverse reactions have been identified during post-approval use of Olumiant. 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.

Immune System Disorders: Drug hypersensitivity (events such as rash, urticaria, and angioedema have been observed).

DRUG INTERACTIONS

Strong OAT3 Inhibitors—Baricitinib exposure is increased when Olumiant is co-administered with strong Organic Anion Transporter 3 (OAT3) inhibitors (such as probenecid), hence the dosage of baricitinib should be reduced by half the recommended dose.

Other JAK Inhibitors or Biologic DMARDs—Olumiant has not been studied in combination with other JAK inhibitors or with biologic DMARDs.

USE IN SPECIFIC POPULATIONS

Pregnancy

Risk Summary—Based on the findings from animal reproduction studies, Olumiant may cause fetal harm during pregnancy. Available data from clinical trials and postmarketing case reports with Olumiant exposure in pregnancy are insufficient to inform a drug-associated risk for major birth defects, miscarriage, or other adverse maternal or fetal outcomes. There are no human data on chronic baricitinib exposure throughout pregnancy. There are risks to the mother and the fetus associated with rheumatoid arthritis in pregnancy. Consider the risks and benefits with chronic use of Olumiant during pregnancy.

In animal embryo-fetal development studies, oral baricitinib administration to pregnant rats and rabbits at exposures equal to and greater than approximately 11 and 46 times the maximum recommended human dose (MRHD) of 4 mg/day, respectively, resulted in reduced fetal body weights, increased embryolethality (rabbits only), and dose-related increases in skeletal malformations. No developmental toxicity was observed in pregnant rats and rabbits treated with oral baricitinib during organogenesis at approximately 2 and 7 times the exposure at the MRHD, respectively. In a pre- and post-natal development study in pregnant female rats, oral baricitinib administration at exposures approximately 24 times the MRHD resulted in reduction in pup viability (increased incidence of stillborn pups and early neonatal deaths), decreased fetal birth weight, reduced fetal body weight gain, decreased cytotoxic T cells on post-natal day (PND) 35 with evidence of recovery by PND 65, and developmental delays that might be attributable to decreased body weight gain. No developmental toxicity was observed at an exposure approximately 5 times the exposure at the MRHD.

The background risks of major birth defects and miscarriage for the indicated population(s) are 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 2-4% and 15-20%, respectively.

Report pregnancies to Eli Lilly and Company at 1-800-LillyRx (1-800-545-5979).

Clinical Considerations—*Disease-Associated Maternal and/or Embryo/Fetal Risk:* Published data suggest that increased disease activity is associated with the risk of developing adverse pregnancy outcomes in women with rheumatoid arthritis. Adverse pregnancy outcomes include preterm delivery (before 37 weeks of gestation), low birth weight (less than 2500 g) infants, and small for gestational age at birth.

Data—*Animal Data:* In an embryofetal development study in pregnant rats, dosed orally during the period of organogenesis from gestation days 6 to 17, baricitinib was teratogenic (skeletal malformations that consisted of bent limb bones and rib anomalies) at exposures equal to or greater than approximately 11 times the MRHD (on an AUC basis at maternal oral doses of 10 mg/kg/day and higher). No developmental toxicity was observed in rats at an exposure approximately 2 times the MRHD (on an AUC basis at a maternal oral dose of 2 mg/kg/day).

In an embryofetal development study in pregnant rabbits, dosed orally during the period of organogenesis from gestation days 7 to 20, embryolethality, decreased fetal body weights, and skeletal malformations (rib anomalies) were observed in the presence of maternal toxicity at an exposure approximately 46 times the MRHD (on an AUC basis at a maternal oral dose of 30 mg/kg/day). Embryolethality consisted of increased post-implantation loss that was due to elevated incidences of both early and late resorptions. No developmental toxicity was observed in rabbits at an exposure approximately 7 times the MRHD (on an AUC basis at a maternal oral dose of 10 mg/kg/day).

In a pre- and post-natal development study in pregnant female rats dosed orally from gestation day 6 through lactation day 20, adverse findings observed in pups included decreased survival from birth to post-natal day 4 (due to increased stillbirths and early neonatal deaths), decreased birth weight, decreased body weight gain during the pre-weaning phase, increased incidence of malrotated forelimbs during the pre-weaning phase, and decreased cytotoxic T cells on PND 35 with recovery by PND 65 at exposures approximately 24 times the MRHD (on an AUC basis at a maternal oral dose of 25 mg/kg/day). Developmental delays (that may be secondary to decreased body weight gain) were observed in males and females at exposures approximately 24 times the MRHD (on an AUC basis at a maternal oral dose of 25 mg/kg/day). These findings included decreased forelimb and hindlimb grip strengths, and delayed mean age of sexual maturity. No developmental toxicity was observed in rats at an exposure approximately 5 times the MRHD (on an AUC basis at a maternal oral dose of 5 mg/kg/day).

Lactation

Risk Summary—No information is available on the presence of Olumiant in human milk, the effects of the drug on the breastfed infant, or the effects of the drug on milk production. Baricitinib is present in the milk of lactating rats. Because of the potential for serious adverse reactions in nursing infants advise women not to breastfeed during treatment with Olumiant and for 4 days after the last dose (approximately 5 to 6 half-lives).

Data—A single oral dose of 25 mg/kg radiolabeled baricitinib was administered to lactating female Sprague-Dawley rats on post-partum day 13. Drug exposure was approximately 45-fold greater in milk than in plasma based on AUC_{0-t} values.

Females and Males of Reproductive Potential

Contraception—Based on animal studies, Olumiant may cause fetal harm when administered during pregnancy. Consider pregnancy planning and prevention for females of reproductive potential.

Pediatric Use—The safety and effectiveness of Olumiant in pediatric patients have not been established.

Geriatric Use—Of the 3100 patients treated in the rheumatoid arthritis clinical trials, a total of 537 patients were 65 years of age and older, including 71 patients 75 years of age and older. Of the 2558 patients treated in the COVID-19 clinical trials, a total of 791 were 65 years of age and older, including 295 patients 75 years and older. No overall differences in safety or effectiveness were observed between these subjects and younger subjects,

OLUMIANT® (baricitinib) BA HCP BS 13JUN2022

and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

Of the 1200 patients in the alopecia areata trials, a total of 29 patients were 65 years of age or older. The number of patients aged 65 years and older was not sufficient to determine whether they respond differently from younger patients.

Olumiant is known to be substantially excreted by the kidney, and the risk of adverse reactions to this drug may be greater in patients with impaired renal function. Because geriatric patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

Hepatic Impairment—No dose adjustment is necessary in patients with mild or moderate hepatic impairment.

The use of Olumiant has not been studied in patients with rheumatoid arthritis or alopecia areata and severe hepatic impairment and is therefore not recommended. Olumiant has not been studied in patients with COVID-19 and severe hepatic impairment. Olumiant should only be used in patients with COVID-19 and severe hepatic impairment if the potential benefit outweighs the potential risk.

Renal Impairment—Renal function was found to significantly affect baricitinib exposure.

Rheumatoid Arthritis and Alopecia Areata**—**The recommended dosage of Olumiant in patients with moderate renal impairment (estimated glomerular filtration rate [GFR] between 30 and <60 mL/min/1.73 m^2) should be reduced by half the recommended dose. Olumiant is not recommended for use in patients with rheumatoid arthritis or alopecia areata and severe renal impairment (estimated GFR of less than 30 mL/min/1.73 m^2).

COVID-19**—**The recommended dosage of Olumiant in patients with moderate renal impairment (estimated GFR between 30 and <60 mL/min/1.73 m^2) or severe renal impairment (estimated GFR between 15 and <30 mL/min/1.73 m^2) is 2 mg once daily and 1 mg once daily, respectively. Olumiant is not recommended for use in patients who are on dialysis, have end-stage renal disease (ESRD), or with estimated GFR of <15 mL/min/1.73 m^2.

OVERDOSAGE

Single doses up to 40 mg and multiple doses of up to 20 mg daily for 10 days have been administered in clinical trials without dose-limiting toxicity. Pharmacokinetic data of a single dose of 40 mg in healthy volunteers indicate that more than 90% of the administered dose is expected to be eliminated within 24 hours.

In case of an overdose, it is recommended that the patient should be monitored for signs and symptoms of adverse reactions. Patients who develop adverse reactions should receive appropriate treatment.

Additional information can be found at www.Olumiant.com

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- Provides a 1 page summary up to a full 24 page comprehensive report

3 SudoMotor Testing

1934

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PAGING ALL RESIDENTS:

Who's looking out for your financial wellness?

If your wallet needs live-saving measures, now is a great time to avert a crisis.

BY ANDY HARMS

The grind. Residents know about it. Long days requiring intense mental focus. Physically demanding. Exhilarating and enjoyable, yet exhausting and overwhelming at times. Loving what we do—but not loving what it does to us on some of those days.

We're a diverse set of people yet bound together by purpose. We can thrive in ever-changing, always-evolving patient care environments and on-call opportunities. Just as well, many of us excel best with a more structured day, one with meticulous order and greater command over outcomes. Our personal identities and varied interests were a large part of how we chose our specialty.

Regardless, as residents we've all been trained to think on our feet, orient and analyze quickly, decide with assurance, and act toward a favorable outcome.

In speaking with residents over the years about personal financial situations, I see an incredible ability for young physicians to manage—if not juggle! —their money matters despite weighty, disorderly, and persistent challenges.

Wouldn't it be nice if there was an easier way to prepare and plan financially, to bring order from chaos? The good news: there IS a better way. The bad news is you likely were NOT trained in finances the same way you trained for medical practice.

The Journal of the American College of Surgeons published a study in 2018 titled "Clinically Competent and Fiscally at Risk: Impact of Debt and Financial Parameters on the Surgical Resident." One hundred five resident trainees were surveyed on topics of personal finance, and the majority (79%) of respondents felt strongly that inclusion of additional financial training in residency education is a critical need. The authors conclude: In a climate of increasingly delayed financial gratification, surgical trainees are on critically unstable financial footing. There is a major gap in current surgical education that requires reassessment for the long-term financial health of residents.

In digging deeper for perspective on resident finances, I spoke with the researcher and author of this study with the longest tenure in medicine, Dr. Bruce Harms, MD, MBA, FACS. "My generation of doctors, I believe, assumed that we could out-grow, with time, any financial mistakes and miscalculations we made in residency and early on in our careers. I think that is an incorrect assumption nowadays. For younger docs, in this era, the mistakes made from a financial standpoint may be extremely costly in the long run." When asked to point out the biggest differences from then (Dr. Harms began residency in 1978) to now, he pointed out "certainly educational debt is the biggest difference I see, but also the cost of living. Housing, transportation, health care and childcare command a significantly greater part of a budget as compared to when I received my start in medicine."

If you're in a residency program that addresses your financial literacy and financial preparation needs well, count your blessings. That's certainly not common throughout

organized medicine in the United States. Similarly, if you're employed in a residency program that offers a retirement plan with matching employer contributions, count yourself fortunate.

So where can we turn for assistance to avoid making costly financial mistakes and confidently face the challenges of personal finance during residency, given it may be unlikely to come through our employers or GME programs?

One of my favorite recommendations for residents hoping for better command over their personal finances is to pick up, digest, and implement suggestions from a book titled MD in the Black: A Personal Finance Primer for Medical Residents. (Please note: I have no ties to the authors or sponsors of this book) It's informative, practical, and concise. For all those in the TL;DR camp, it's only a hundred pages. I recognize your time is limited—among the barriers to better financial literacy—but reading this book is certainly worth making a priority. Editor-in-Chief Eric Shappell, MD, MHPE, and physician educators from around the United States created a great resource, specifically designed for residents.

The book focuses on five topics: 1) Educational debt, 2) Long-term disability insurance, 3) Life insurance, 4) Investing, and 5) Financial advisors

Likely you have questions in all these areas. The authors point out "they are each related to a significant financial decision that the majority of residents will encounter during training."

We won't breakdown each major category here, of course, but I would like to highlight two takeaways that every reader of this article at the residency level should consider:

First, on the topic of educational debt: Have you asked yourself "What is Public Service Loan Forgiveness?" and "Should I Pursue PSLF?" This is the first decision you should make, and various sources can help you better understand how to approach this process of determination. Once a determination is made regarding PSLF, a debt repayment strategy can be mapped out further.

As important as long-term disability insurance, life insurance, and investing are to the needs of a resident, a personal and in-depth commentary on each is beyond the scope and space of this article. However, they are a good lead-in to the second point we'd like to highlight here from Dr. Shappell's book, considering the question "Should I Hire a Financial Advisor in Residency?"

Most residents should be able to get along just fine with only a few hours dedicated to researching the basic financial decisions of residency (1) choosing a loan repayment plan, (2) choosing which insurance products to purchase and when, and (3) what to do with any extra income (typically a decision of whether to make extra payments on loans vs. invest). If you don't feel comfortable making these decisions on your own and aren't interested in learning more about them yourself, choosing to hire a financial advisor may be the way to go. This also may be a good idea if you have unusually complex financial circumstances. (Shappell 84)

Whether during residency or as an attending, the likely outcome in any event is a search for an experienced and trusted financial advisor. What credentials do you seek, what questions do you ask? MD in the Black notes residents looking to start at the ground-level in forming a financial plan will do well to consider an advisor with a Certified Financial Planner (CFP), Chartered Financial Consultant (ChFC) or Certified Public Accountant/Personal Financial Specialist (CPA/PFS) designation. Additionally, I suggest aiming to find a Fee-Only advising arrangement, particularly for planning services. This model minimizes conflicts and ensures that your financial planner acts as a fiduciary. Fee-Only planners are compensated directly by their clients for advice, plan implementation and for the ongoing management of assets. Fee-only financial advisors may be paid hourly, as a retainer, as a percentage of assets under management, or as a flat fee, depending upon the planner you choose.

As residents, we understand the importance of preventative health care and the consequences of delayed treatment. This understanding, applied to our personal finances, will not only stave off a trip to the financial ED (i.e., more borrowing, lower net worth, less financial freedom), but enable us to enjoy the peace of mind and sense of confidence that comes with financial health. Our goal should be to confine the chaotic moments and stressors related to medicine to the hospital and away from our pocketbooks.

We invite you to check out the resources mentioned above and reach out for help at any time to gain better financial understanding, set financial goals, and establish a path to financial wellness. Residency may be the best time to reach out, while the time is still on your side.

—

Andy Harms is co-founder of ScrubMoney, a free app now available for download, providing financial literacy and relevant personal financial content. ScrubMoney aims to empower early-career physicians to achieve financial wellness and enable stakeholders in healthcare to better develop financially confident doctors within their organizations.

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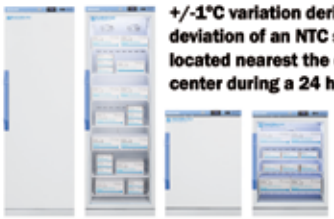
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ARG6PV	6 cu.ft.	32.5"	23.5"	25"	Glass	$1,266.00
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ARG8PV	8 cu.ft.	50"	23.38"	25"	Glass	$1,667.00
ARS12PV	12 cu.ft.	61.75"	23.38"	24.5"	White	$2,139.00
ARG12PV	12 cu.ft.	61.75"	23.38"	25"	Glass	$2,152.00
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ARS49ML	49 cu.ft.	83.75	55.25	31	(2) Stainless	$4,674.00
ARG49ML	49 cu.ft.	83.75	55.25	31	(2) Glass	$5,031.00

Pharma-Lab Freezers

Accucold	Capacity	Height	Width	Depth	Door	PRICE
AFS23ML	23 cu.ft.	83.75	27.5	31	(1) Stainless	$3,205.00
AFS49ML	49 cu.ft.	83.75	55.25	31	(2) Stainless	$5,194.00

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2 Match your maximum doses with the minimum cubic feet needed to safely store your vaccine

Max. Doses	Minimum Cubic Ft.
2,000+ doses	may need more than one refrigerator
1000-2000	40 cu.ft
900-1000	36 cu.ft
801-900	21-23 cu.ft
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