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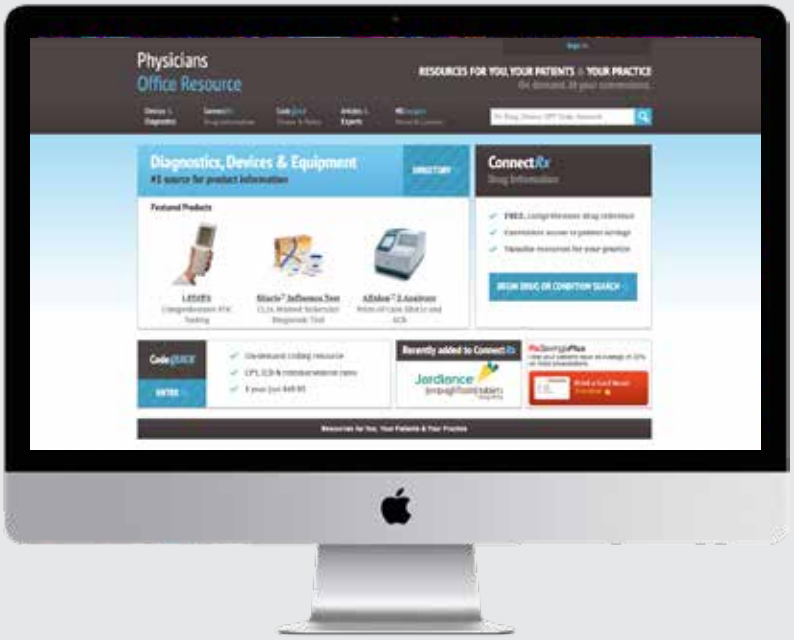
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Diabetes Patient Management:
The Pros, The Cons, and the Costs of Insulin Pump Therapy

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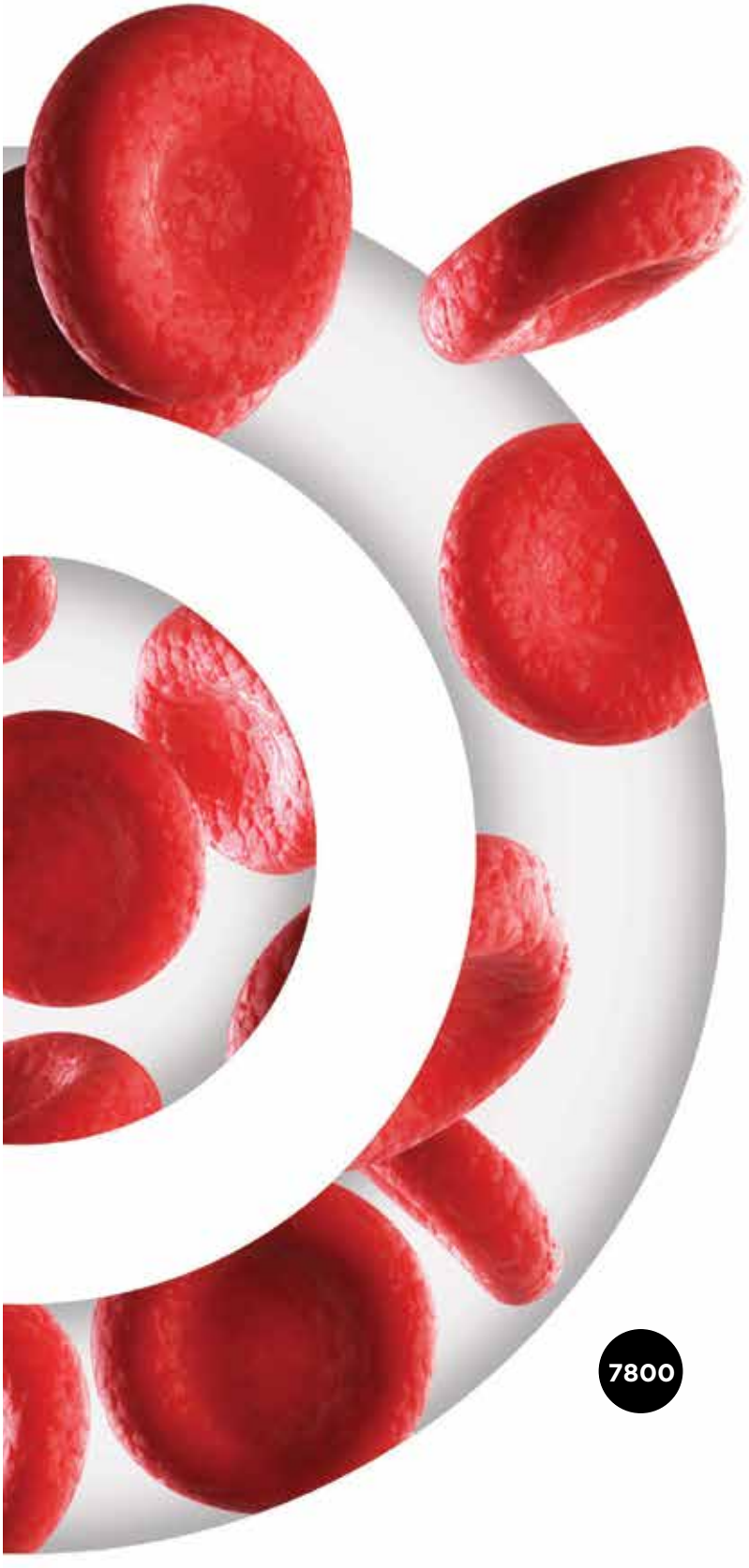
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Diabetes Patient Management:
The Pros, The Cons, and the Costs of Insulin Pump Therapy

Insulin pump therapy has long been recognized as one of the most effective therapy options for both Type 1 and intensively managed Type 2 patients. There are hundreds if not thousands of studies that have shown how the use of an insulin pump improves patient outcomes. Over the years insulin pumps have made some substantial leaps in terms of usability features and benefits.

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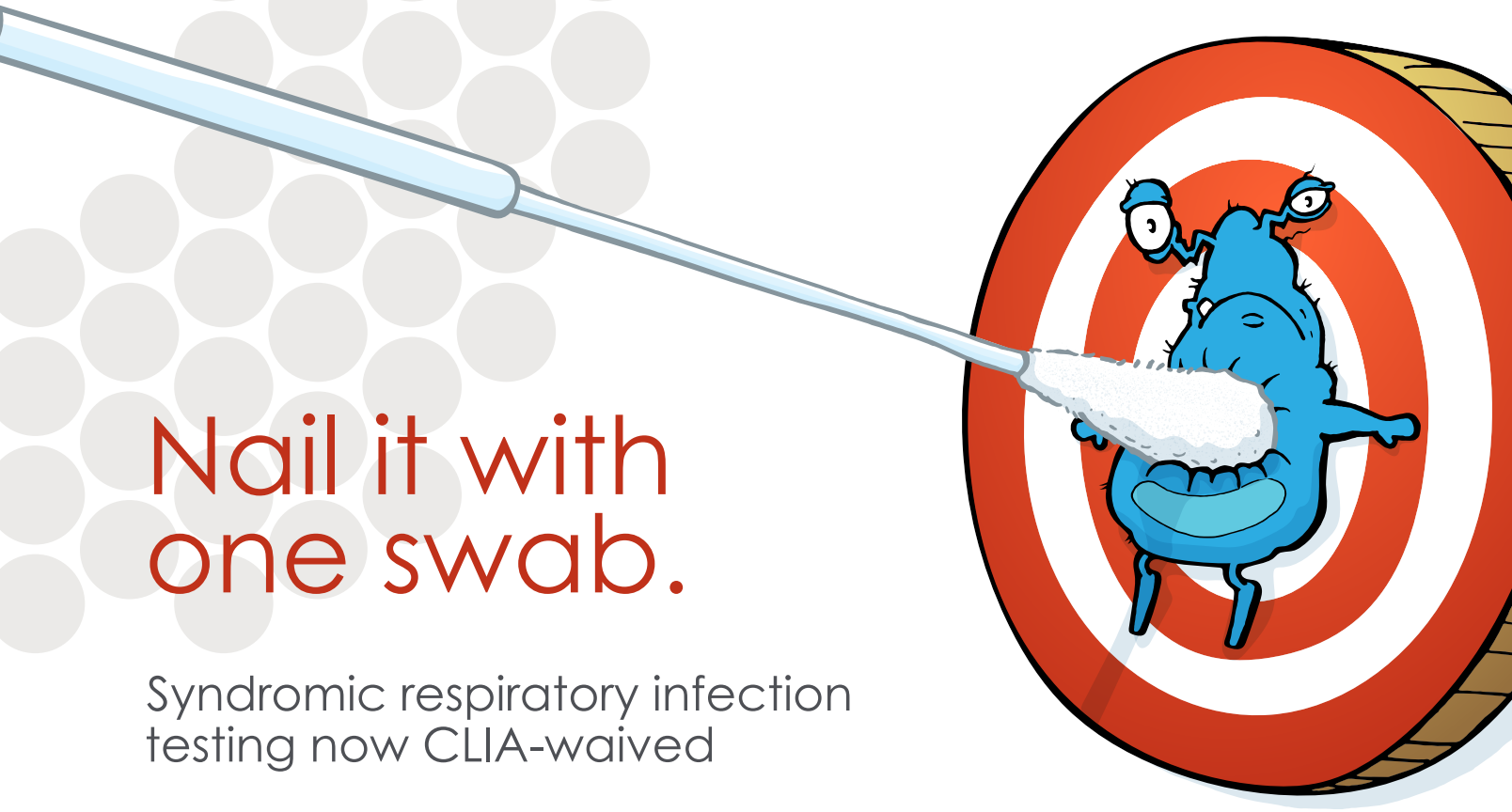
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DIABETES PATIENT MANAGEMENT:

The Pros, The Cons, and the Costs of Insulin Pump Therapy

BY DAVID KLIFF, THE DIABETIC INVESTOR

Insulin pump therapy has long been recognized as one of the most effective therapy options for both Type 1 and intensively managed Type 2 patients. There are hundreds if not thousands of studies that have shown how the use of an insulin pump improves patient outcomes. Over the years insulin pumps have made some substantial leaps in terms of usability features and benefits. While more complex than multiple daily injection (MDI) therapy, insulin pump therapy has also become more patients and physician friendly.

In this column we'll examine the pros and cons of insulin pump therapy with a focus on the intensively managed Type 2 population. We'll pay very close attention to the latest sensor augmented systems given the increasing usage of continuous glucose monitoring (CGM) Please also note, it's pretty easy for an existing pump patient to switch from one system to another, therefore our comments here will focus more on patients initiating pump therapy for the first time. With that said, let's begin.

The Pros

Thankfully, because of CGM technology initiating pump therapy has never been easier. In fact, we would go as far and state that no patient should initiate pump therapy without being on a CGM for at least 30 days (60 or 90 would be better). Why? Using the software that works with the existing CGM system it becomes simple to determine several of the factors that are used to program the pump. Factors such as:

· Insulin time to action
· Duration of action
· Insulin to Carb Ratio's

CGM data also provides a more detailed overview which allows for better pump programming. For example, given that pumps now allow for multiple basal rates, should a patient be experiencing dawn phenomenon, the pump can be programmed to deal with this issue. owever Now thanks to technology we have two systems and soon a


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third where the CGM and pump are designed to work together. There is the 670G from Medtronic and the Control IQ from Tandem; Insulet will soon have the Horizon on the market sometime later this year. These hybrid closed loop systems offer several benefits; most notably is that the majority of the heavy lifting decisions that patients used to make are now being made by the system. Using sophisticated insulin dosing algorithms, these systems can almost be like an auto pilot on an airplane managing the patient's insulin dosing.

These systems are designed to keep patients in a tighter range with the additional benefit of protecting patients from dangerous hypoglycemic events. Should the system detect a hypoglycemic event coming it automatically shuts down the delivery of insulin while warning the patient of pending low. On the flip side, should the system detect the patient's glucose going outside their range on the high side it automatically delivers insulin keeping the patient in range.

Frankly the real-world results of these new systems has been astonishing with patients achieving Time In Range (TIR), a key new very important metric for measuring control, of greater than 70%. More astonishing is achieving these ranges with few adverse hypoglycemic events. Although the Control IQ has not been available for as long as the 670G, the real-world results are nothing short of fantastic with patients achieving TIR of greater than 85%.

Although we have yet to see detailed data on the coming Horizon system from Insulet, we suspect it will perform as well as the Control IQ as it works with the same CGM system, Dexcom and has a similar insulin dosing algorithm. The fact is when it comes to insulin pumps in today's world the pump itself is just a piece of programmable hardware, the real work is done by the CGM and the insulin dosing algorithm. However, we should note that patients have indicated the user interface for the Control IQ is much more patient friendly than the 670G interface.

Insulin pump therapy has long been recognized as one of the most effective therapy options for both Type 1 and intensively managed Type 2 patients.

The Cons

Now as way cool and whiz bang as these new systems are, they do not come without drawbacks. First and foremost, they are medical devices, and unfortunately medical devices can and do malfunction. This is fact of life with any medical device and insulin pumps are no different. The big difference is these systems deliver insulin which is not just a life sustaining drug but also a lethal drug when incorrectly dosed. While deaths are very rare with these systems they have occurred.

Secondarily, as sophisticated as these systems have become, they do not function without patient interaction. Infusion sets needed to change every three days, reservoirs replaced and filled every three days, sensors replaced every 10 days, etc. The pump itself needs to



charge with a typical charge lasting a day perhaps two. The reality is some patients just don't want to do all this stuff and find it easier to inject even if that means injecting multiple times per day.

Third, there is training and an adjustment period for patients new to pump therapy. Yes, pumps are much smarter these days as they are basically minicomputers, but even with this advanced technology patients still need training. There is also an adjustment period as the patient transitions from MDI to insulin pump therapy. A period which not only impacts their outcomes but mindset as well. Some patients experience a feeling of relief or freedom when put on these systems no longer worrying about having their insulin with them or having to inject in a public place. Others feel somewhat anxious as they realize they are attached to a machine which for all practical purposes has control over their lives and until they trust the system this anxiety will remain. Obviously, each patient is different which is why we recommend patients new to pump therapy also work with a CDE who can help them deal with these issues.

The Costs

Now no discussion of insulin pump therapy would be complete without discussing the financial ramifications. With the exception of the OmniPod system from Insulet, pump therapy is not cheap and does require ongoing costs to the patient. Add in the cost of a CGM and it's understandable why some patients chose to excuse the expression stick with MDI. Even the OmniPod which requires no upfront cost nor any costs for pump supplies does require an ongoing cost.

Before advising any patient on whether to implement pump therapy we'd highly recommend a discussion on this issue of cost. As we all know diabetes besides being a chronic disease is also a costly disease and given the complexities of health insurance coverage the cost of diabetes sometimes can and does interfere with the management of diabetes. No one likes this situation however it is better to address this issue up front.

There is no question that insulin pump therapy has made tremendous advancements these past few years. However, this does not in any way mean insulin pump therapy is for everyone. As we have noted there are several critical issues that may prevent a patient from transitioning from MDI to pump therapy. Still, given the results we are seeing in the real world with the newer sensor augmented systems, it's hard to ignore the potential of insulin pump therapy.



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†RSV- Respiratory Syncytial Virus

References:
1. BD Veritor System for Rapid Detection of Flu A+B, CLIA-waived kit package insert, 8087667 (14) 2018-06.
BD Veritor System for Rapid Detection of Flu A+B, laboratory kit package insert, 8087666 (11) 2017-10.

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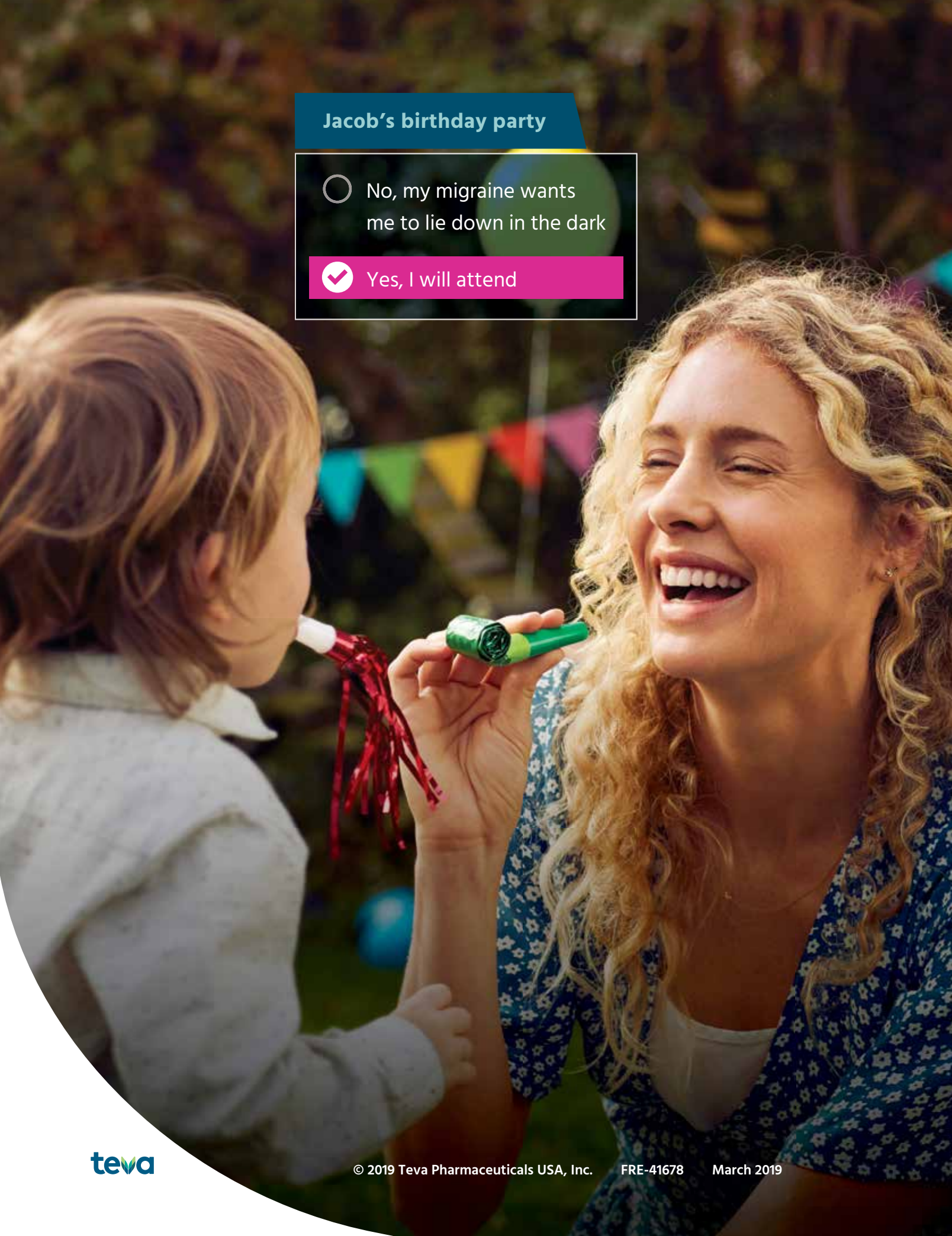


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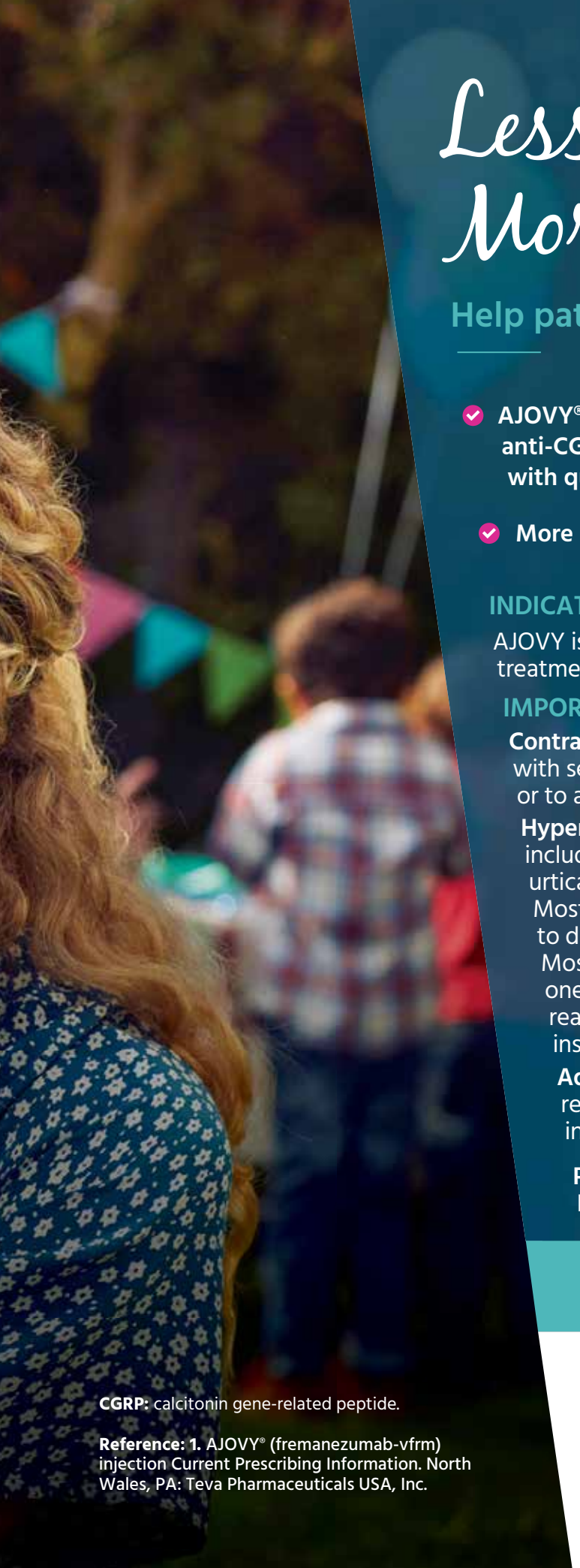
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Help patients say yes to more moments

- **AJOVY® (fremanezumab-vfrm) injection is the only anti-CGRP treatment for the prevention of migraine with quarterly and monthly dosing options[1]**
- **More migraine-free days with AJOVY in clinical trials[1]**

INDICATION

AJOVY is indicated for the preventive treatment of migraine in adults.

IMPORTANT SAFETY INFORMATION

Contraindications: AJOVY is contraindicated in patients with serious hypersensitivity to fremanezumab-vfrm or to any of the excipients.

Hypersensitivity Reactions: Hypersensitivity reactions, including rash, pruritus, drug hypersensitivity, and urticaria were reported with AJOVY in clinical trials. Most reactions were mild to moderate, but some led to discontinuation or required corticosteroid treatment. Most reactions were reported from within hours to one month after administration. If a hypersensitivity reaction occurs, consider discontinuing AJOVY and institute appropriate therapy.

Adverse Reactions: The most common adverse reactions (≥5% and greater than placebo) were injection site reactions.

Please see Brief Summary of full Prescribing Information on the following page.

To learn more, visit AJOVYhcp.com

AJOVY®
(fremanezumab-vfrm)
injection 225 mg/1.5 mL

CGRP: calcitonin gene-related peptide.

Reference: 1. AJOVY® (fremanezumab-vfrm) injection Current Prescribing Information. North Wales, PA: Teva Pharmaceuticals USA, Inc.

BRIEF SUMMARY OF PRESCRIBING INFORMATION FOR
AJOVY® (fremanezumab-vfrm) injection, for subcutaneous use
SEE PACKAGE INSERT FOR FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

AJOVY is indicated for the preventive treatment of migraine in adults.

2 DOSAGE AND ADMINISTRATION

2.1 Recommended Dosage

Two subcutaneous dosing options of AJOVY are available to administer the recommended dosage:

- 225 mg monthly, or
- 675 mg every 3 months (quarterly), which is administered as three consecutive subcutaneous injections of 225 mg each.

When switching dosage options, administer the first dose of the new regimen on the next scheduled date of administration. If a dose of AJOVY is missed, administer as soon as possible. Thereafter, AJOVY can be scheduled from the date of the last dose.

2.2 Important Administration Instructions

AJOVY is for subcutaneous use only.

AJOVY may be administered by healthcare professionals, patients, and/or caregivers. Prior to use, provide proper training to patients and/or caregivers on the preparation and administration of AJOVY prefilled syringe, including aseptic technique *[see Instructions for Use in full Prescribing Information]*.

- Remove AJOVY from the refrigerator. Prior to use, allow AJOVY to sit at room temperature for 30 minutes protected from direct sunlight. Do not warm by using a heat source such as hot water or a microwave. Do not use AJOVY if it has been at room temperature for 24 hours or longer.
- Follow aseptic injection technique every time AJOVY is administered.
- Inspect AJOVY for particles or discoloration prior to administration. Do not use if the solution is cloudy, discolored, or contains particles.
- Administer AJOVY by subcutaneous injection into areas of the abdomen, thigh, or upper arm that are not tender, bruised, red, or indurated. For multiple injections, you may use the same body site, but not the exact location of the previous injection.
- Do not co-administer AJOVY with other injectable drugs at the same injection site.

4 CONTRAINDICATIONS

AJOVY is contraindicated in patients with serious hypersensitivity to fremanezumab-vfrm or to any of the excipients *[see Warnings and Precautions (5.1)]*.

5 WARNINGS AND PRECAUTIONS

5.1 Hypersensitivity Reactions

Hypersensitivity reactions, including rash, pruritus, drug hypersensitivity, and urticaria, were reported with AJOVY in clinical trials. Most reactions were mild to moderate, but some led to discontinuation or required corticosteroid treatment. Most reactions were reported from within hours to one month after administration.

If a hypersensitivity reaction occurs, consider discontinuing AJOVY, and institute appropriate therapy.

6 ADVERSE REACTIONS

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

- Hypersensitivity Reactions *[see Warnings and Precautions (5.1)]*

6.1 Clinical Trials Experience

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

The safety of AJOVY was evaluated in 2512 patients with migraine who received at least 1 dose of AJOVY, representing 1279 patient-years of exposure. Of these, 1730 patients were exposed to AJOVY 225 mg monthly or AJOVY 675 mg quarterly for at least 6 months, 775 patients for at least 12 months, and 138 patients for at least 15 months. In placebo-controlled clinical trials (Studies 1 and 2), 662 patients received AJOVY 225 mg monthly for 12 weeks (with or without a loading dose of 675 mg), and 663 patients received AJOVY 675 mg quarterly for 12 weeks. In the controlled trials, 87% of patients were female, 80% were White, and the mean age was 41 years.

The most common adverse reactions in the clinical trials for the preventive treatment of migraine (incidence at least 5% and greater than placebo) were injection site reactions. The adverse reactions that most commonly led to discontinuations were injection site reactions (1%). Table 1 summarizes adverse reactions reported in the 3-month placebo-controlled studies (Study 1 and Study 2), and the 1-month follow-up period after those studies.

Table 1: Adverse Reactions Occurring with an Incidence of At Least 2% for Either Dosing Regimen of AJOVY and At Least 2% Greater Than Placebo in Studies 1 and 2

Adverse Reaction	AJOVY 225 mg Monthly (n=290) %	AJOVY 675 mg Quarterly (n=667) %	Placebo Monthly (n=668) %
Injection site reactions[a]	43	45	38

[a] Injection site reactions include multiple related adverse event terms, such as injection site pain, induration, and erythema.

6.2 Immunogenicity

As with all therapeutic proteins, there is a potential for immunogenicity. The detection of antibody formation is highly dependent on sensitivity and specificity of the assay. Additionally, the observed incidence of antibody (including neutralizing antibody) positivity in an assay may be influenced by several factors, including assay methodology, sample handling, timing of sample collection, concomitant medications, and underlying disease. For these reasons, comparison of the incidence of antibodies to fremanezumab-vfrm in the studies described below with the incidence of antibodies in other studies to other products may be misleading. Clinical immunogenicity of AJOVY was monitored by analyzing anti-drug antibodies (ADA) and neutralizing antibodies in drug-treated patients. The data reflect the percentage of patients whose test results were positive for antibodies to AJOVY in specific assays.

In 3-month placebo-controlled studies, treatment-emergent ADA responses were observed in 6 out of 1701 (0.4%) AJOVY-treated patients. One of the 6 patients developed anti-AJOVY neutralizing antibodies at Day 84. In the ongoing long-term open-label study, ADA were detected in 1.6% of patients (30 out of 1888). Out of 30 ADA-positive patients, 17 had a neutralizing activity in their post-dose samples. Although these data do not demonstrate an impact of anti-fremanezumab-vfrm antibody development on the efficacy or safety of AJOVY in these patients, the available data are too limited to make definitive conclusions.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

There are no adequate data on the developmental risk associated with the use of AJOVY in pregnant women. AJOVY has a long half-life. This should be taken into consideration for women who are pregnant or plan to become pregnant while using AJOVY. Administration of fremanezumab-vfrm to rats and rabbits during the period of organogenesis or to rats throughout pregnancy and lactation at doses resulting in plasma levels greater than those expected clinically did not result in adverse effects on development *[see Animal Data]*. 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. The estimated rate of major birth defects (2.2-2.9%) and miscarriage (17%) among deliveries to women with migraine are similar to rates reported in women without migraine.

Clinical Considerations

Disease-Associated Maternal and/or Embryo/Fetal Risk

Published data have suggested that women with migraine may be at increased risk of preeclampsia during pregnancy.

Data

Animal Data

When fremanezumab-vfrm (0, 50, 100, or 200 mg/kg) was administered to male and female rats by weekly subcutaneous injection prior to and during mating and continuing in females throughout organogenesis, no adverse embryofetal effects were observed. The highest dose tested was associated with plasma exposures (AUC) approximately 2 times that in humans at a dose of 675 mg.

Administration of fremanezumab-vfrm (0, 10, 50, or 100 mg/kg) weekly by subcutaneous injection to pregnant rabbits throughout the period of organogenesis produced no adverse effects on embryofetal development. The highest dose tested was associated with plasma AUC approximately 3 times that in humans (675 mg).

Administration of fremanezumab-vfrm (0, 50, 100, or 200 mg/kg) weekly by subcutaneous injection to female rats throughout pregnancy and lactation resulted in no adverse effects on pre- and postnatal development. The highest dose tested was associated with plasma AUC approximately 2 times that in humans (675 mg).

8.2 Lactation

Risk Summary

There are no data on the presence of fremanezumab-vfrm in human milk, the effects on the breastfed infant, or the effects on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for AJOVY and any potential adverse effects on the breastfed infant from AJOVY or from the underlying maternal condition.

8.4 Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

8.5 Geriatric Use

Clinical studies of AJOVY did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects.

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This Brief Summary is based on the full Prescribing Information for AJOVY AJO-002.

teva

FRE-41620 March 2019



New COVID-19 test to differentiate between lethal and non-lethal infections

A ground-breaking test for the potentially fatal COVID-19 strain of coronavirus, is available at global health diagnostics company Randox Laboratories.

The test, developed on Randox's patented Biochip Technology, is as an enhanced multiplex array which includes tests for COVID-19 and nine other respiratory viruses which can display the same symptoms.

The new enhanced Biochip therefore allows clinicians to quickly and efficiently differentiate between potentially lethal and non-lethal infections.

Dr Peter FitzGerald, Managing Director of Randox Laboratories, commented;

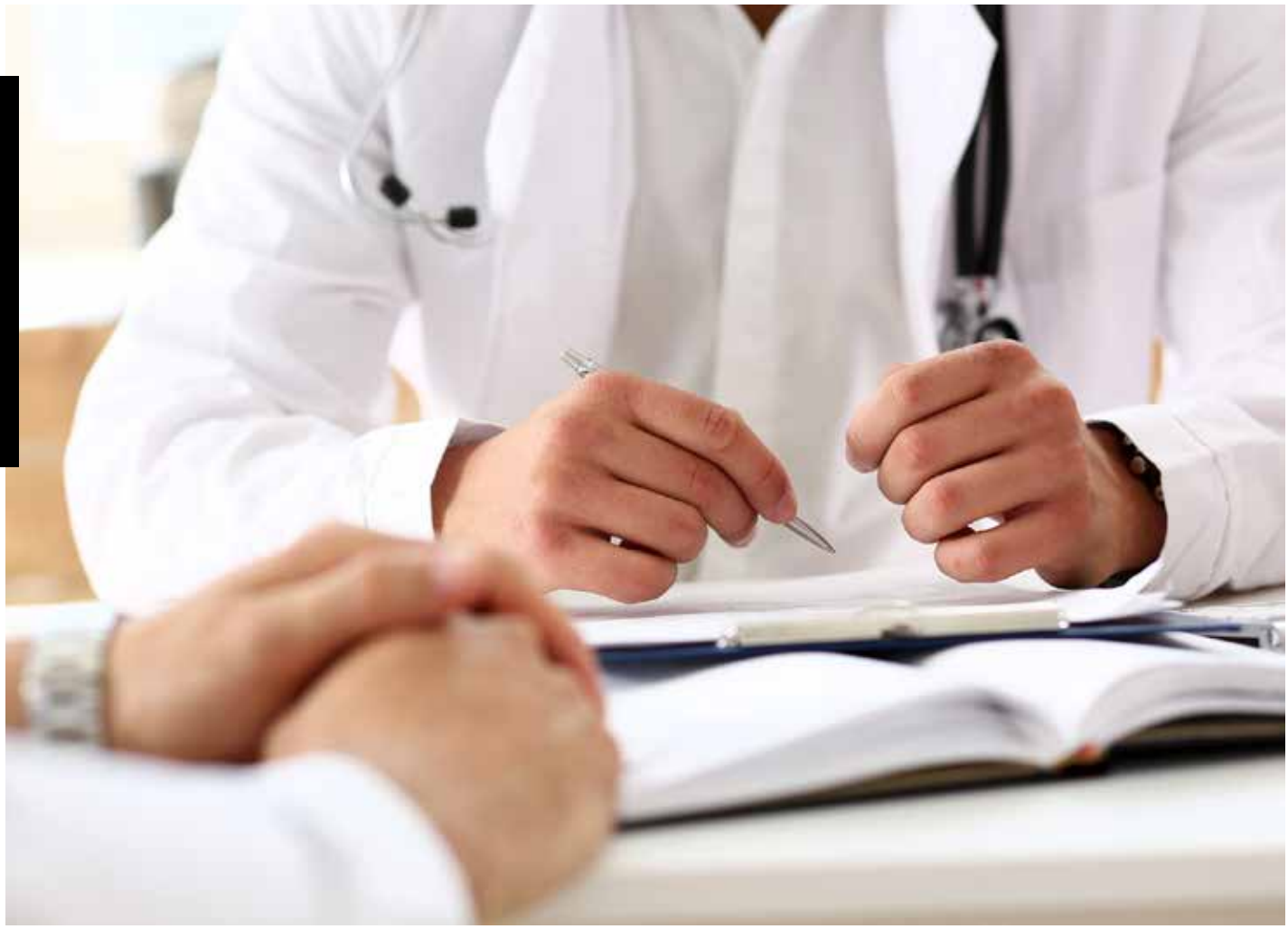
"Current technologies for the diagnosis of coronavirus are designed simply to detect the presence or lack of COVID-19, and therefore neglect to differentiate between this strain and other respiratory infections.

"We have therefore developed an extended Viral Respiratory Infection Array that tests simultaneously for COVID-19 and nine other viruses. This will eliminate the need for multiple back-and-forth tests before the root cause of symptoms is found, and empower clinicians to make fast and informed decisions."

The test is available on the Randox Evidence Investigator with a turnaround time of 5 hours.

Benefits of the new Randox COVID-19 test

- Quick Turnaround Times (5 hours on Evidence Investigator)
- Multiplex array differentiates between mild and serious infection
- Automated and Semi-Automated options available
- Medium to high throughput (54 samples in 5 hours)



PSA:

TO SCREEN OR NOT TO SCREEN? THAT IS THE QUESTION...

BY SEKISUI DIAGNOSTICS

There are certain milestones in life that no one looks forward to—having your wisdom teeth pulled. That first mammogram! At the top of the list for men is likely that first rectal exam at 40 or 50 as an initial screening for prostate cancer. But, like those pesky wisdom teeth and the oh-so-important mammogram, screening for prostate cancer is important and necessary.

A policy paper produced by the European Association of Urology1 states that there were approximately 450,000 cases of prostate cancer in Europe in 2018 and 107,000 deaths expected. In 2019, the American Cancer Society estimates2 that there will be about 174,650 new cases of prostate cancer in the U.S. Globally prostate cancer3 is the second most commonly occurring cancer in men and the fourth most commonly occurring cancer overall.

That being said, prostate cancer often can be treated successfully. In fact, the localized and regional five-year survival rates4 for this type of cancer are near 100%! As with all cancers, early diagnosis is important. Most prostate cancers are first found5 during screening with a prostate-specific antigen (PSA) blood test or a digital rectal exam (DRE). While prostate cancers usually don't cause symptoms in the early stages, more advanced cancers are sometimes first found because of symptoms they cause.

So why are there ongoing controversial discussions about PSA screening? Why do the United States and Europe hold different positions regarding some aspects of screening?

So What's the Deal?

How can one argue that it's better not to screen for a cancer? The medical community is divided due to the risk of overdiagnosis and overtreatment. Cancer overdiagnosis6 is the detection of cancer that would not develop any symptoms during a man's lifetime if not identified by early detection or not result in cancer-related death. Overtreatment refers to unnecessary medical interventions, including extensive treatment for a condition that requires only limited treatment.

According to the European Association of Urology1, the risk of overdiagnosis has been estimated to be as high as 40% in screen-detected prostate cancer, leading to unnecessary biopsies and detection of insignificant cancers, which could lead to overtreatment. In 2012, the U.S. Preventive Services Task Force (USPSTF) actually recommended against7 screening for prostate cancer in all men! However in 2017, the USPSTF released a new draft recommendation for prostate cancer screening encouraging providers7 to inform men ages 55 to 69 about the benefits and harms of prostate cancer screening.

Worrying Statistics

Practitioners in both the UK and the U.S.1 were advised not to perform PSA for early detection. Two independent studies performed in 2017 and 2018 found that a lack of prostate cancer screening may be reversing1 the trend of declining death rates—meaning mortality from these type of cancer could be on the rise. This year, the European Association of Urology made a call to action8, stating, "Urgent action is required to ensure the new Commission is mandated to support EU Member States in prostate cancer screening in their national cancer plans."

EAU Policy Coordinator Michelle Battye wants the 2003 Council Recommendations on population-based screening to be "urgently reviewed," with prostate cancer added to the list of cancers to be addressed, and wants member states to bring good practice on prostate cancer screening to the Steering Group on Health Promotion, Disease Prevention and Management of non-communicable diseases.

How the U.S. Responded

As we briefly mentioned above, in 2017 the USPSTF released new recommendation for prostate cancer screening encouraging providers7 to inform men ages 55 to 69 about the benefits and harms of prostate cancer screening. The American Cancer Society recommends9 that men learn as much as they can about prostate cancer screening risks and benefits and discuss the information with their doctor before deciding whether to be tested. Men at average risk of prostate cancer should have this discussion at age 50. Men at higher than average risk should have the discussion starting at age 40 or 45.

The consequences of decreased PSA screening[10] are numerous:

- *Increased mortality*
- *The effects of non-curative intervention*
- *Psychological complications of recurrent prostate cancer*

So do the risks of prostate cancer screening outweigh the benefits? That's not a question any man should answer alone—he should discuss the pros and cons of screening with his doctor to make an informed decision. However, physicians should bring this topic to the table at the appropriate time for all affected patients.

In the end, prostate cancer screening is important, as it is with all types of available cancer screenings. A little bit of research can inundate you with statistics, recommendations, and lots of other frightening material. What matters is that physicians are aware of recommended guidelines and available screening and treatment options, and that patients are given the information they need to make informed decisions regarding their health.

That being said, prostate cancer often can be treated successfully. In fact, the localized and regional five-year survival rates for this type of cancer are near 100%!

Sekisui Diagnostics offers two tests (please note that only one is currently available in the U.S.). The FastPack® IP Total PSA immunoassay11 is a chemiluminescent immunoassay for the in-vitro quantitative determination of PSA in human serum and plasma as an aid in the management of patients with prostate cancer. It offers results in 12 minutes.

The FastPack® IP Free PSA Immunoassay12, not currently available in the U.S., is a chemiluminescent immunoassay for the in-vitro quantitative determination of free prostate-specific antigen (free PSA) in human serum. It is designed for use in conjunction with the FastPack IP System for calculating the ratio of free/total PSA, expressed as a percentage (percent free PSA). A free PSA test13 can be used instead of a biopsy if PSA levels are slightly elevated, and may be used to determine how aggressive a recurring cancer is.

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[1] (BD Veritor System for Rapid Detection of Flu A+B, CLIA-waved kit package insert, 8087667 (14) 2018-06. BD Veritor System for Rapid Detection of Flu A+B, laboratory kit package insert, 8087666 (11) 2017-10., 2018-06.)

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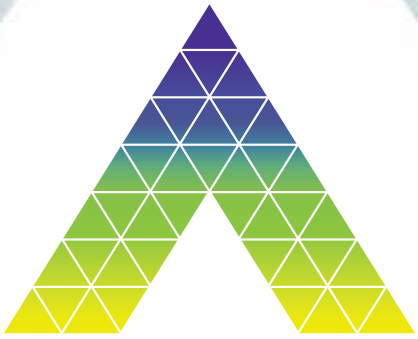


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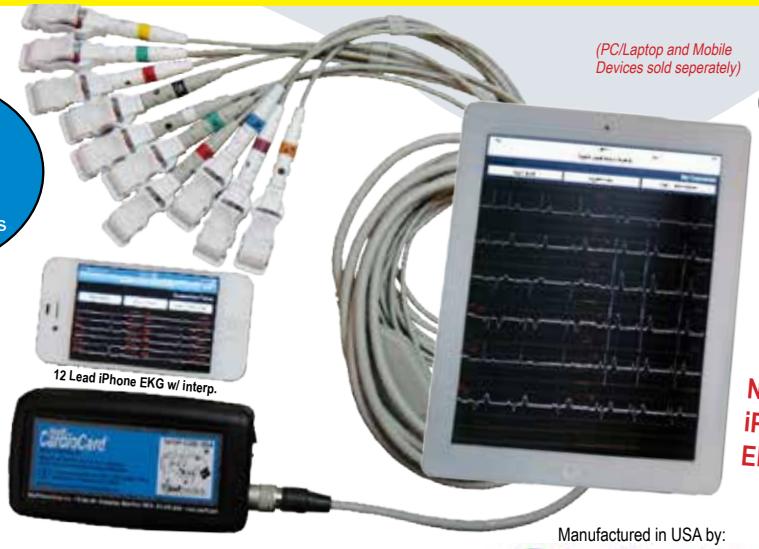
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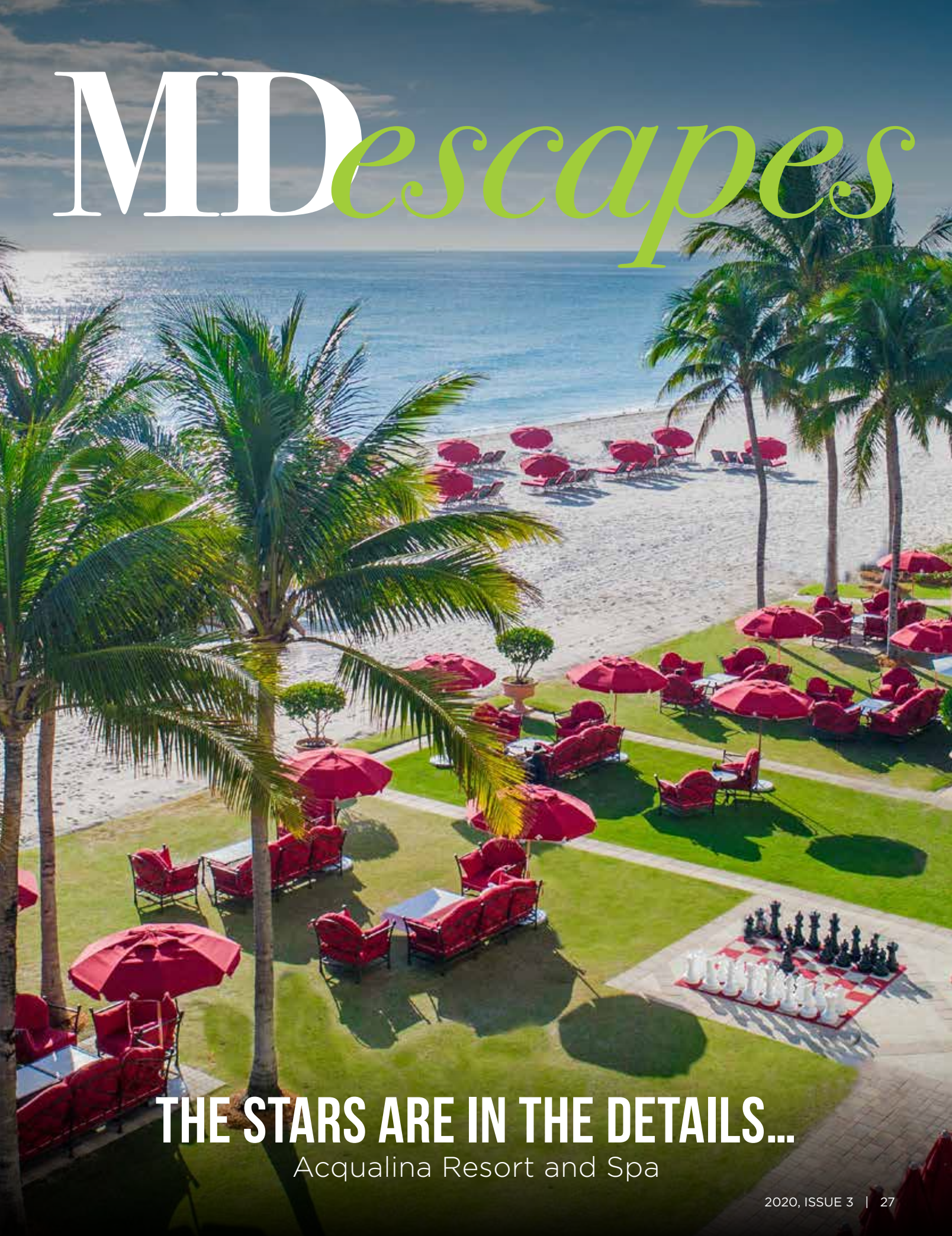
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MDescapes



THE STARS ARE IN THE DETAILS...

Acqualina Resort and Spa



THE STARS ARE IN THE DETAILS...

Acqualina Resort and Spa

BY BRANDI BROWER, TRAVEL EDITOR

Just north of Miami, there's a special place. White drapes with red trim tied back from the arched alcove, wisp in the light wind, waving a welcome as my car drives up the brick-paved incline to the several young valets dressed in a pressed white shirts trimmed in red. Just ahead is a Venetian statue in the middle of six water fountains in a pool of blue, flanked by some of the most beautiful luxury cars that I've ever seen. This resort is home to the highest collection of independently owned Rolls Royce vehicles out of any property in the world. For an instant, I regretted my choice of a rental car, as my Ford Fusion seems a bit out of place as the smiling valet graciously opened my door and offered to take my luggage.

"Welcome to Acqualina," the suited doormen say in unison as they in tandem open up the oversized doors into the entrance of the lavish hotel. The Mediterranean-inspired resort has the relaxed vibe of Collins Avenue with the sophistication of a Venetian palace. As you enter the stunning lobby with high arched ceiling, massive iron chandeliers, gold leaf, and marble columns, you feel as though you're no longer in Florida, or even the United States. During the prompt check-in process, I was offered a cooled scented towel and a choice of water, champagne, or Bellini. As Mardy, the Front Desk Agent gave me the guided tour of the main floor where works of art on display feature rare prints and portraits, including the likes of Andy Warhol and Roy



Lichtenstein. Because the resort entertains a partnership with Fine Arts Miami, the contemporary wall art are not prints or duplicates, but the originals, and value far exceeds the cost of my room during my stay.

I actually wouldn't classify it as just a room, as every guest accommodation feels like a suite. Even the standard Intracoastal rooms, with their spacious balconies and 640 feet of living space, would be classified as a junior suite anywhere else with the full-sized living area, oversized marble bathroom with spacious walk-in shower and separate Jacuzzi tub. The resort structure itself is massive, the 51-floor building hosts three towers, the two exteriors are exclusively private residential while the center portion of the building houses the resort's guest rooms. There are only 98 rooms and suites that make up the hotel. Each floor houses only four to five guest rooms, combine that and the spacious accommodations, evokes the unique feeling of privacy as it's more like residential living than staying in a hotel room. General Manager, Christof Pignet, shares a goal for the resort patrons, "We want our guests to feel as though they are staying with family or in the home of a good friend."

When I arrived at my room, I was a bit stunned by the opulence of modern design as the suite was sprawling and utterly magnificent. As much as I love the grandeur of the resort lobby, I enjoyed the surprising level of sophisticated comfort that the suite afforded. The design pallet of calming tones, cream, champagne, white, ash grey with textured satin, high gloss lacquer, metallic and faux fur accents are all brought together for a sleek aesthetic and yet very homey and comfortable. Almost too comfortable as I toured the entire set up and questioned why I would ever want to leave? An office, with built-in desk, bookshelves, desktop computer, and a daybed, was to the right of the entry hall. A comfortable living area with beautiful furnishings opens up to a very spacious veranda overlooking the Atlantic. Natural light floods the space, as does sweeping views of the beach below. An entire wall of floor to ceiling glass doors welcome in the lovely blue hues of the ocean, adding an accent of color to the calming tones of the suite. To my left, a full kitchen with a dining room table, Illy espresso machine, granite countertops, and Wolf appliances. (When your resort suite has a better kitchen than you have at our own home.) A full stocked fridge replaces the usual minibar, and the freezer has a surprise stash of mini Haagen-Dazs ice cream tubs, bless their little Dulce de Leche hearts. The king-size bed with Frette linens and goose down duvets almost guarantees a pleasant rest and with a large slider opening onto the patio, insuring a spectacular ocean view.

The bathroom, both expansive and indulgent with marble floors, double sinks, bench and vanity, Jacuzzi tub complete with yummy bath salts, large enclosed shower with both rain shower head and handheld nozzle, and even a bidet. (When in Rome ~ keeping with that European feel) But it's the little things that make life sweet; a half bath just off the living room, ESPA toiletries and the soft robes with the branded "A" clover monogrammed on the cuff. As well, slippers with the "A" clover also prominent, the "A" clover etched in the sliding doors, not one but two huge flat-screen T.V.s, a walk-in closet, and a vanity mirror, to name a few sweet extra touches. They even remembered the rubber ducky with a tongue in cheek message attached, "No one should bathe alone at Acqualina." For the guests who love to read but forgot their book at home, the resort offers their Bedside Reading Program which shares best sellers on the bedside tables for guests to enjoy during their stay. I ask myself again, why would I ever want to leave my six-room suite of respite?

The resort is only one of its kind to be built entirely open to the sea, free of any barriers between the resort tower and four hundred feet of gorgeous shoreline. I'm certain that this is the genesis for the name of the privately owned hotel, proudly built by the Trump brothers from South Africa, (no relation). As they roughly translate Acqualina as the "water's edge" and have created this beautiful resort at the edge of Atlantic blue aqua.

Just one look off of my terrace to the glistening white sand, verdant palms, azure waters, and red beach umbrellas dotted below and I'm inspired to explore the colors that are Acqualina. Keeping with the Mediterranean ambiance, Acqualina's signature outdoor living room settings with comfy crimson couches and chairs and matching umbrellas and low tables create intimate clusters to gather family and friends. It feels like you're on the Italian Riviera, soaking up the sun somewhere between the south of France and Tuscany. Isaiah approaches me and introduces himself and asks if this was my first time visiting. He also inquires how I would like to be addressed during my stay. I'm not sure if the young attendant will see me again but I let him know my first name is excellent.

He guides me over to a waiting beach cabana with a pitcher of ice water waiting and towel-lined lounge chairs. I'm curious how he likes working at the resort and ask what makes Acqualina so unique that people keep coming back? "The stars are in the details'" he proclaims proudly, "Having attention to detail is important because a small deal to me could be a big deal for someone else. Like refreshing water and ice, even if they didn't need it, or remembering a person's name." Isaiah smiled and ended his thought with, "Little things matter."



If official accolades and awards matter to you, Acqualina has chalked up many of the highest honors in the hospitality industry. Forbes Five Star for eight consecutive years, AAA's Five Diamond Award for twelve straight years, USA Today #1 Best Waterfront Hotel, #1 Family Resort in the World, Trip Advisor Travelers Choice Award for Top Luxury Beachfront Resort in the Continental U.S. and Andrew Harper Readers' Choice Awards named Acqualina the #1 beach resort, spa resort and family resort in the world. Stars and Diamonds aside, what matters most is your personal experience. As Isaiah put it, "The stars are in the details…little things matter."

Acqualina has three swimming pools to ensure all guests have a choice for their water / sunbathing activities. Attentive pool staff offers luxury service, which is commensurate with the Acqualina brand. This service includes the presentation of hourly amenities like chilled fruit, smoothies, iced coffees, as well as the signature Thai coconut water drinks served in a coconut shell embossed with the branded "A" clover (an Instagram worthy photo). The Beach Club Pool is the largest, with the popular zero entry, arched fountains, and is where all guests can enjoy activities and lounge. The Recreation Pool is where staff organizes fitness classes and games for children. The Tranquility Pool is an adults-only space with hot tub, optional private cabanas, an excellent place for optimal relaxation and to set yourself apart from the more active crowd. Lunch and Snacks are served at all pools and the beach.

There is no reason to leave the premises to dine elsewhere as there are three exquisite restaurants to serve up anything your heart desires. Costa Grill is the beach/pool haunt that serves lunch and libations. I raised my little red flag while at the beach and received prompt service with my Lio's Tacos prepared with the fresh catch of the day. I also enjoyed a lovely Mediterranean platter at the outdoor seating another afternoon. The food is casual, along with the setting and the view was amazing. Whether it's a beautiful breakfast buffet by day or a sumptuous filet mignon by night, A.Q. by Il Mulino with both indoor and outdoor dining, is a lovely place to fulfill your cuisine cravings. Beautiful oversized windows allowed the morning light to fill the spacious restaurant as I enjoyed my delicious French toast and planned my day. By night, the ambiance is enhanced with the famous artwork and a giant, 1930s art-deco style chandelier that hangs from the lofty ceiling. The cuisine is modern steak house meets Mediterranean flair. Famed Miami sushi chefs from Yakko-San offer a full Sushi and raw bar, creating delectable bites from the East, serving up specials that include crunchy spicy tuna rolls and salmon sashimi.

I saved the best gastronomic experience for last, Il Mulino New York. Take the famous #1 Italian restaurant on the NYC Zagat survey for an astounding 20 years and mix that with the Mediterranean vibe of the Acqualina and it is a match made in hospitality heaven. I loved this culinary occasion so much that I went back a second night. The Maître d', Carlos, graciously sat me at a quaint table for two, next to the glass-paned mahogany framed double doors that looks out over the pool and further on to the ocean. Stunning tapestries hang on the walls; large mahogany antique sideboards adorned with wine bottles flank the floor to ceiling windows; above are iron chandeliers that provide the mood lighting. It is as though I have stepped out of South Florida and into Southern Italy. Andrea Bocelli and Frank Sinatra serenade as the head waiter, Jose, dressed in a tuxedo, brings the old world charm. He first offers the complimentary amuse bouche, which was a spicy fried zucchini. The waiter then cut pieces of 24-month aged Parmesan cheese and served that with a selection of five different types of Bruschetta. My starter, a traditional spinach salad with bacon and mushrooms that tasted better than I've ever tasted. The next evening I had Caprese as a starter and, once again, the best that I've ever tasted. As the main course, I chose one of the restaurant's signature dishes of Ravioli ai Porcini with champagne truffle cream sauce. I am usually a very slow eater, but I acted as if someone was going to take my plate away from me. It was one of the most delicious things I've ever consumed. The Gueridon service brought a unique ambiance to the meal, watching the head waiter, cook, and finish the dish in front of me was mesmerizing. The next night, I was tempted to order the same main course but promised myself I'd be back for another visit and ordered the delicious Capellini Milano, a pink sauce, with pancetta, sweet peas, mushrooms, and black truffle. I passed on the blueberry Grappa that they served from a "magical" copper kettle, but said yes to a flourless chocolate cake with Sabayon cream and berries. It was an incredible meal for the memory book.

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For adult patients with type 2 diabetes, treated with diet and exercise

REALIZE THE POTENTIAL



Choose Ozempic® as your first injectable— the only once-weekly GLP-1 RA with superior results vs Trulicity®[1,2]

SUPERIOR GLYCEMIC CONTROL

SUPERIOR WEIGHT REDUCTION

Ozempic® is not indicated for weight loss.

CV SAFETY

as evaluated in a 2-year CVOT.[2]

Ozempic® is not indicated for reduction in major adverse CV events (MACE).

SUSTAIN 6: A 2-year, randomized, multinational, double-blind, placebo-controlled, parallel-group CV safety trial that was designed to assess noninferiority of Ozempic® vs standard of care by excluding the preapproval noninferiority margin of 1.8. A total of 3297 adult patients with type 2 diabetes and high risk of CV events were randomized based on evidence of CV disease, insulin treatment, and renal impairment to once-weekly Ozempic® 0.5 mg (n=826), Ozempic® 1 mg (n=822), or placebo (n=1649) in addition to standard of care treatments such as oral antidiabetic treatments, insulin, antihypertensives, diuretics, lipid-lowering therapies, and antithrombotic medication at investigator discretion. The primary composite endpoint was the time from randomization to first occurrence of a MACE, defined as CV death, nonfatal myocardial infarction, or nonfatal stroke.[3]

Indication and Limitations of Use

Ozempic® (semaglutide) injection 0.5 mg or 1 mg is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

- Ozempic® is not recommended as a first-line therapy for patients who have inadequate glycemic control on diet and exercise because of the uncertain relevance of rodent C-cell tumor findings to humans.
- Ozempic® has not been studied in patients with a history of pancreatitis. Consider other antidiabetic therapies in patients with a history of pancreatitis.
- Ozempic® is not a substitute for insulin. Ozempic® is not indicated for use in patients with type 1 diabetes mellitus or for the treatment of patients with diabetic ketoacidosis.

Important Safety Information

WARNING: RISK OF THYROID C-CELL TUMORS

- **In rodents, semaglutide causes dose-dependent and treatment-duration-dependent thyroid C-cell tumors at clinically relevant exposures. It is unknown whether Ozempic® causes thyroid C-cell tumors, including medullary thyroid carcinoma (MTC), in humans as human relevance of semaglutide-induced rodent thyroid C-cell tumors has not been determined.**
- **Ozempic® is contraindicated in patients with a personal or family history of MTC and in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2). Counsel patients regarding the potential risk for MTC with the use of Ozempic® and inform them of symptoms of thyroid tumors (e.g. a mass in the neck, dysphagia, dyspnea, persistent hoarseness). Routine monitoring of serum calcitonin or using thyroid ultrasound is of uncertain value for early detection of MTC in patients treated with Ozempic®.**

Contraindications

- Ozempic® is contraindicated in patients with a personal or family history of MTC or in patients with MEN 2, and in patients with known hypersensitivity to semaglutide or to any of the product components.

Warnings and Precautions

- **Risk of Thyroid C-Cell Tumors:** Patients should be referred to an endocrinologist for further evaluation if serum calcitonin is measured and found to be elevated or thyroid nodules are noted on physical examination or neck imaging.
- **Pancreatitis:** Acute and chronic pancreatitis have been reported in clinical studies. Observe patients carefully for signs and symptoms of pancreatitis (persistent severe abdominal pain, sometimes radiating to the back with or without vomiting). If pancreatitis is suspected, discontinue Ozempic® promptly, and if pancreatitis is confirmed, do not restart.
- **Diabetic Retinopathy Complications:** In a 2-year trial involving patients with type 2 diabetes and high cardiovascular risk, more events of diabetic retinopathy complications occurred in patients treated with Ozempic® (3.0%) compared to placebo (1.8%). The absolute risk increase for diabetic retinopathy complications was larger among patients with a history of diabetic retinopathy at baseline than among patients without a known history of diabetic retinopathy.

  Rapid improvement in glucose control has been associated with a temporary worsening of diabetic retinopathy. The effect of long-term glycemic control with semaglutide on diabetic retinopathy complications has not been studied. Patients with a history of diabetic retinopathy should be monitored for progression of diabetic retinopathy.

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In a 40-week trial, in patients on metformin, for each dose comparison

Ozempic® was superior to Trulicity® in A1C and weight reduction[1]

ONCE-WEEKLY OZEMPIC® semaglutide injection 0.5mg|1mg



Ozempic® outperformed Trulicity® in reducing A1C[1]

–1.4% with **Ozempic® 0.5 mg** (Baseline: 8.3%) vs
–1.1% with **Trulicity® 0.75 mg** (Baseline: 8.2%); *P*=0.002

–1.6% with **Ozempic® 1 mg** (Baseline: 8.2%) vs
–1.3% with **Trulicity® 1.5 mg** (Baseline: 8.2%); *P*=0.0004



Secondary endpoint

Ozempic® demonstrated superior body weight reduction vs Trulicity®[1]

Ozempic® is not indicated for weight loss.

–9.3 lb with **Ozempic® 0.5 mg** (Baseline: 213 lb) vs
–4.6 lb with **Trulicity® 0.75 mg** (Baseline: 211 lb); ETD=–4.7 lb (95% CI; –6.5, –2.9)

–12.8 lb with **Ozempic® 1 mg** (Baseline: 211 lb) vs
–6.2 lb with **Trulicity® 1.5 mg** (Baseline: 206 lb); ETD=–6.7 lb (95% CI; –8.5, –5.0)

SUSTAIN 7: A 40-week, multinational, multicenter, randomized, open-label, four-armed, pair-wise, active-controlled, parallel-group trial to compare the efficacy and safety of Ozempic® vs dulaglutide. A total of 1201 adult patients with type 2 diabetes inadequately controlled on metformin were randomized to receive Ozempic® 0.5 mg (n=301), Ozempic® 1 mg (n=300), dulaglutide 0.75 mg (n=299), or dulaglutide 1.5 mg (n=299) once weekly. The primary endpoint was mean change in A1C from baseline at Week 40. Secondary endpoints included mean change in body weight at Week 40 and proportion of patients achieving A1C <7% at Week 40. Results based on a sensitivity analysis of retrieved dropout population.[1]

Learn more about Ozempic® and the CVOT at ***OzempicPro.com***.

- **Never Share an Ozempic® Pen Between Patients:** Ozempic® pens must never be shared between patients, even if the needle is changed. Pen-sharing poses a risk for transmission of blood-borne pathogens.
- **Hypoglycemia:** The risk of hypoglycemia is increased when Ozempic® is used in combination with insulin secretagogues (e.g., sulfonylureas) or insulin.
- **Acute Kidney Injury:** There have been postmarketing reports of acute kidney injury and worsening of chronic renal failure, which may sometimes require hemodialysis, in patients treated with GLP-1 receptor agonists. Some of these events have been reported in patients without known underlying renal disease. A majority of the reported events occurred in patients who had experienced nausea, vomiting, diarrhea, or dehydration. Monitor renal function when initiating or escalating doses of Ozempic® in patients reporting severe adverse gastrointestinal reactions.
- **Hypersensitivity:** Serious hypersensitivity reactions (e.g., anaphylaxis, angioedema) have been reported with GLP-1 receptor agonists. If hypersensitivity reactions occur, discontinue use of Ozempic®; treat promptly per standard of care, and monitor until signs and symptoms resolve. Use caution in a patient with a history of angioedema or anaphylaxis with another GLP-1 receptor agonist.
- **Macrovascular Outcomes:** There have been no clinical studies establishing conclusive evidence of macrovascular risk reduction with Ozempic®.

Adverse Reactions

- The most common adverse reactions, reported in ≥5% of patients treated with Ozempic® are nausea, vomiting, diarrhea, abdominal pain, and constipation.

Drug Interactions

- The risk of hypoglycemia may be lowered by a reduction in the dose of the secretagogue or insulin.
- Ozempic® causes a delay of gastric emptying and has the potential to impact the absorption of concomitantly administered oral medications, so caution should be exercised.

Use in Specific Populations

- There are limited data with semaglutide use in pregnant women to inform a drug-associated risk for adverse developmental outcomes. Discontinue Ozempic® in women at least 2 months before a planned pregnancy due to the long washout period for semaglutide.

Please see Brief Summary of Prescribing Information on following pages.

GLP-1 RA=glucagon-like peptide-1 receptor agonist; CV=cardiovascular; CVOT=cardiovascular outcomes trial; ETD=estimated treatment difference; CI=confidence interval.

References: 1. Pratley RE, Aroda VR, Lingvay I, et al. Semaglutide versus dulaglutide once weekly in patients with type 2 diabetes (SUSTAIN 7): a randomised, open-label, phase 3b trial. *Lancet Diabetes Endocrinol.* 2018;6(4):275-286. **2.** Ozempic [package insert]. Plainsboro, NJ: Novo Nordisk Inc; 2017. **3.** Marso SP, Bain SC, Consoli A, et al. Semaglutide and cardiovascular outcomes in patients with type 2 diabetes. *N Engl J Med.* 2016;375(19):1834-1844.

ONCE-WEEKLY OZEMPIC® semaglutide injection 0.5mg|1mg

OZEMPIC® (semaglutide) injection

Rx Only

BRIEF SUMMARY: Please consult package insert for full prescribing information.

WARNING: RISK OF THYROID C-CELL TUMORS: In rodents, semaglutide causes dose-dependent and treatment-duration-dependent thyroid C-cell tumors at clinically relevant exposures. It is unknown whether OZEMPIC® causes thyroid C-cell tumors, including medullary thyroid carcinoma (MTC), in humans as human relevance of semaglutide-induced rodent thyroid C-cell tumors has not been determined *[see Warnings and Precautions]*. OZEMPIC® is contraindicated in patients with a personal or family history of MTC or in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2) *[see Contraindications]*. Counsel patients regarding the potential risk for MTC with the use of OZEMPIC® and inform them of symptoms of thyroid tumors (e.g. a mass in the neck, dysphagia, dyspnea, persistent hoarseness). Routine monitoring of serum calcitonin or using thyroid ultrasound is of uncertain value for early detection of MTC in patients treated with OZEMPIC® *[see Contraindications and Warnings and Precautions]*.

INDICATIONS AND USAGE: OZEMPIC® is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Limitations of Use: OZEMPIC® is not recommended as a first-line therapy for patients who have inadequate glycemic control on diet and exercise because of the uncertain relevance of rodent C-cell tumor findings to humans *[see Warnings and Precautions]*. OZEMPIC® has not been studied in patients with a history of pancreatitis. Consider other antidiabetic therapies in patients with a history of pancreatitis *[see Warnings and Precautions]*. OZEMPIC® is not a substitute for insulin. OZEMPIC® is not indicated for use in patients with type 1 diabetes mellitus or for the treatment of patients with diabetic ketoacidosis, as it would not be effective in these settings.

CONTRAINDICATIONS: OZEMPIC® is contraindicated in patients with: A personal or family history of medullary thyroid carcinoma (MTC) or in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2) *[see Warnings and Precautions]*; Known hypersensitivity to semaglutide or to any of the product components *[see Warnings and Precautions]*.

WARNINGS AND PRECAUTIONS: Risk of Thyroid C-Cell Tumors: In mice and rats, semaglutide caused a dose-dependent and treatment-duration-dependent increase in the incidence of thyroid C-cell tumors (adenomas and carcinomas) after lifetime exposure at clinically relevant plasma exposures. It is unknown whether OZEMPIC® causes thyroid C-cell tumors, including medullary thyroid carcinoma (MTC), in humans as human relevance of semaglutide-induced rodent thyroid C-cell tumors has not been determined. Cases of MTC in patients treated with liraglutide, another GLP-1 receptor agonist, have been reported in the postmarketing period; the data in these reports are insufficient to establish or exclude a causal relationship between MTC and GLP-1 receptor agonist use in humans. OZEMPIC® is contraindicated in patients with a personal or family history of MTC or in patients with MEN 2. Counsel patients regarding the potential risk for MTC with the use of OZEMPIC® and inform them of symptoms of thyroid tumors (e.g. a mass in the neck, dysphagia, dyspnea, persistent hoarseness). Routine monitoring of serum calcitonin or using thyroid ultrasound is of uncertain value for early detection of MTC in patients treated with OZEMPIC®. Such monitoring may increase the risk of unnecessary procedures, due to the low test specificity for serum calcitonin and a high background incidence of thyroid disease. Significantly elevated serum calcitonin value may indicate MTC and patients with MTC usually have calcitonin values >50 ng/L. If serum calcitonin is measured and found to be elevated, the patient should be further evaluated. Patients with thyroid nodules noted on physical examination or neck imaging should also be further evaluated. **Pancreatitis:** In glycemic control trials, acute pancreatitis was confirmed by adjudication in 7 OZEMPIC®-treated patients (0.3 cases per 100 patient years) versus 3 in comparator-treated patients (0.2 cases per 100 patient years). One case of chronic pancreatitis was confirmed in an OZEMPIC®-treated patient. In a 2-year trial, acute pancreatitis was confirmed by adjudication in 8 OZEMPIC®-treated patients (0.27 cases per 100 patient years) and 10 placebo-treated patients (0.33 cases per 100 patient years), both on a background of standard of care. After initiation of OZEMPIC®, observe patients carefully for signs and symptoms of pancreatitis (including persistent severe abdominal pain, sometimes radiating to the back and which may or may not be accompanied by vomiting). If pancreatitis is suspected, OZEMPIC® should be discontinued and appropriate management initiated; if confirmed, OZEMPIC® should not be restarted. **Diabetic Retinopathy Complications:** In a 2-year trial involving patients with type 2 diabetes and high cardiovascular risk, more events of diabetic retinopathy complications occurred in patients treated with OZEMPIC® (3.0%) compared to placebo (1.8%). The absolute risk increase for diabetic retinopathy complications was larger among patients with a history of diabetic retinopathy at baseline (OZEMPIC® 8.2%, placebo 5.2%) than among patients without a known history of diabetic retinopathy (OZEMPIC® 0.7%, placebo 0.4%). Rapid improvement in glucose control has been associated with a temporary worsening of diabetic retinopathy. The effect of long-term glycemic control with semaglutide on diabetic retinopathy complications has not been studied. Patients with a history of diabetic retinopathy should be monitored for progression of diabetic retinopathy. **Never Share an OZEMPIC® Pen Between Patients:** OZEMPIC® pens must never be shared between patients, even if the needle is changed. Pen-sharing poses a risk for transmission of blood-borne pathogens. **Hypoglycemia with Concomitant Use of Insulin Secretagogues or Insulin:** The risk of hypoglycemia is increased when OZEMPIC® is used in combination with insulin secretagogues (e.g., sulfonylureas) or insulin. Patients may require a lower dose of the secretagogue or insulin to reduce the risk of hypoglycemia in this setting *[see Adverse Reactions, Drug Interactions]*. **Acute Kidney Injury:** There have been postmarketing reports of acute kidney injury and worsening of chronic renal failure, which may sometimes require hemodialysis, in patients treated with GLP-1 receptor agonists. Some of these events have been reported in patients without known underlying renal disease. A majority of the reported events occurred in patients who had experienced nausea, vomiting, diarrhea, or dehydration. Monitor renal function when initiating or escalating doses of OZEMPIC® in patients reporting severe adverse gastrointestinal reactions. **Hypersensitivity:** Serious hypersensitivity reactions (e.g., anaphylaxis, angioedema) have been reported with GLP-1 receptor agonists. If hypersensitivity reactions occur, discontinue use of OZEMPIC®; treat promptly per standard of care, and monitor until signs and symptoms resolve. Do not use in patients with a previous hypersensitivity to OZEMPIC® *[see Contraindications]*. Anaphylaxis and angioedema have been reported with other GLP-1 receptor agonists. Use caution in a patient with a history of angioedema or anaphylaxis with another GLP-1 receptor agonist because it is unknown whether such patients will be predisposed to anaphylaxis with OZEMPIC®. **Macrovascular Outcomes:** There have been no clinical studies establishing conclusive evidence of macrovascular risk reduction with OZEMPIC®.

ADVERSE REACTIONS: The following serious adverse reactions are described below or elsewhere in the prescribing information: Risk of Thyroid C-cell Tumors *[see Warnings and Precautions]*; Pancreatitis *[see Warnings and Precautions]*; Diabetic Retinopathy Complications *[see Warnings and Precautions]*; Hypoglycemia with Concomitant Use of Insulin Secretagogues or Insulin *[see Warnings and Precautions]*; Acute Kidney Injury *[see Warnings and Precautions]*; Hypersensitivity *[see Warnings and Precautions]*. **Clinical Trials Experience:** Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice. Pool of Placebo-Controlled Trials: The data in Table 1 are derived from 2 placebo-controlled trials (1 monotherapy trial and 1 trial in combination with basal insulin) in patients with type 2 diabetes. These data reflect exposure of 521 patients to OZEMPIC® and a mean duration of exposure to OZEMPIC® of 32.9 weeks. Across the treatment arms, the mean age of patients was 56 years, 3.4% were 75 years or older and 55% were male. In these trials 71% were White, 7% were Black or African American, and 19% were Asian; 21% identified as Hispanic or Latino ethnicity. At baseline, patients had type 2 diabetes for an average of 8.8 years and had a mean HbA_{1c} of 8.2%. At baseline, 8.9% of the population reported retinopathy. Baseline estimated renal function was normal (eGFR ≥90 mL/min/1.73m^2) in 57.2%, mildly impaired (eGFR 60 to 90 mL/min/1.73m^2) in 35.9% and moderately impaired (eGFR 30 to 60 mL/min/1.73m^2) in 6.9% of patients. Pool of Placebo- and Active-Controlled Trials: The occurrence of adverse reactions was also evaluated in a larger pool of patients with type 2 diabetes participating in 7 placebo- and active-controlled glycemic control trials including two trials in Japanese patients evaluating the use of OZEMPIC® as monotherapy and add-on therapy to oral medications or insulin. In this pool, a total of 3150 patients with type 2 diabetes were treated with OZEMPIC® for a mean duration of 44.9 weeks. Across the treatment arms, the mean age of patients was 57 years, 3.2% were 75 years or older and 57% were male. In these trials, 60% were White, 6% were Black or African American, and 31% were Asian; 16% identified as Hispanic or Latino ethnicity. At baseline, patients had type 2 diabetes for an average of 8.2 years and had a mean HbA_{1c} of 8.2%. At baseline, 7.8% of the population reported retinopathy. Baseline estimated renal function was normal (eGFR ≥90 mL/min/1.73m^2) in 63.1%, mildly impaired (eGFR 60 to 90 mL/min/1.73m^2) in 34.3%, and moderately impaired (eGFR 30 to 60 mL/min/1.73m^2) in 2.5% of the patients. Common Adverse Reactions: Table 1 shows common adverse reactions, excluding hypoglycemia, associated with the use of OZEMPIC® in the pool of placebo-controlled trials. These adverse reactions occurred more commonly on OZEMPIC® than on placebo, and occurred in at least 5% of patients treated with OZEMPIC®.

Table 1. Adverse Reactions in Placebo-Controlled Trials Reported in ≥5% of OZEMPIC®-Treated Patients with Type 2 Diabetes Mellitus

Adverse Reaction	Placebo (N=262) %	OZEMPIC® 0.5 mg (N=260) %	OZEMPIC® 1 mg (N=261) %
Nausea	6.1	15.8	20.3
Vomiting	2.3	5.0	9.2
Diarrhea	1.9	8.5	8.8
Abdominal pain	4.6	7.3	5.7
Constipation	1.5	5.0	3.1

In the pool of placebo- and active-controlled trials and in the 2-year cardiovascular outcomes trial, the types and frequency of common adverse reactions, excluding hypoglycemia, were similar to those listed in Table 1. *Gastrointestinal Adverse Reactions:* In the pool of placebo-controlled trials, gastrointestinal adverse reactions occurred more frequently among patients receiving OZEMPIC® than placebo (placebo 15.3%, OZEMPIC® 0.5 mg 32.7%, OZEMPIC® 1 mg 36.4%). The majority of reports of nausea, vomiting, and/or diarrhea occurred during dose escalation. More patients receiving OZEMPIC® 0.5 mg (3.1%) and OZEMPIC® 1 mg (3.8%) discontinued treatment due to gastrointestinal adverse reactions than patients receiving placebo (0.4%). In addition to the reactions in Table 1, the following gastrointestinal adverse reactions with a frequency of <5% were associated with OZEMPIC® (frequencies listed, respectively, as: placebo; 0.5 mg; 1 mg): dyspepsia (1.9%, 3.5%, 2.7%), eructation (0%, 2.7%, 1.1%), flatulence (0.8%, 0.4%, 1.5%), gastroesophageal reflux disease (0%, 1.9%, 1.5%), and gastritis (0.8%, 0.8%, 0.4%). Other Adverse Reactions: *Hypoglycemia:* Table 2 summarizes the incidence of events related to

hypoglycemia by various definitions in the placebo-controlled trials.

Table 2. Hypoglycemia Adverse Reactions in Placebo-Controlled Trials In Patients with Type 2 Diabetes Mellitus

	Placebo	OZEMPIC® 0.5 mg	OZEMPIC® 1 mg
Monotherapy			
(30 weeks)	**N=129**	**N=127**	**N=130**
Severe†	0%	0%	0%
Documented symptomatic (≤70 mg/dL glucose threshold)	0%	1.6%	3.8%
Severe† or Blood Glucose Confirmed Symptomatic (≤56 mg/dL glucose threshold)	1.6%	0%	0%
Add-on to Basal Insulin with or without Metformin			
(30 weeks)	**N=132**	**N=132**	**N=131**
Severe†	0%	0%	1.5%
Documented symptomatic (≤70 mg/dL glucose threshold)	15.2%	16.7%	29.8%
Severe† or Blood Glucose Confirmed Symptomatic (≤56 mg/dL glucose threshold)	5.3%	8.3%	10.7%

†"Severe" hypoglycemia adverse reactions are episodes requiring the assistance of another person.

Hypoglycemia was more frequent when OZEMPIC® was used in combination with a sulfonylurea *[see Warnings and Precautions]*. Severe hypoglycemia occurred in 0.8% and 1.2% of patients when OZEMPIC® 0.5 mg and 1 mg, respectively, was co-administered with a sulfonylurea. Documented symptomatic hypoglycemia occurred in 17.3% and 24.4% of patients when OZEMPIC® 0.5 mg and 1 mg, respectively, was co-administered with a sulfonylurea. Severe or blood glucose confirmed symptomatic hypoglycemia occurred in 6.5% and 10.4% of patients when OZEMPIC® 0.5 mg and 1 mg, respectively, was co-administered with a sulfonylurea. Injection Site Reactions: In placebo-controlled trials, injection site reactions (e.g., injection-site discomfort, erythema) were reported in 0.2% of OZEMPIC®-treated patients. Increases in Amylase and Lipase: In placebo-controlled trials, patients exposed to OZEMPIC® had a mean increase from baseline in amylase of 13% and lipase of 22%. These changes were not observed in placebo-treated patients. Cholelithiasis: In placebo-controlled trials, cholelithiasis was reported in 1.5% and 0.4% of patients-treated with OZEMPIC® 0.5 mg and 1 mg, respectively. Cholelithiasis was not reported in placebo-treated patients. Increases in Heart Rate: In placebo-controlled trials, OZEMPIC® 0.5 mg and 1 mg resulted in a mean increase in heart rate of 2 to 3 beats per minute. There was a mean decrease in heart rate of 0.3 beats per minute in placebo-treated patients. Fatigue, Dysgeusia and Dizziness: Other adverse reactions with a frequency of >0.4% were associated with OZEMPIC® include fatigue, dysgeusia and dizziness. **Immunogenicity:** Consistent with the potentially immunogenic properties of protein and peptide pharmaceuticals, patients treated with OZEMPIC® may develop anti-semaglutide antibodies. The detection of antibody formation is highly dependent on the sensitivity and specificity of the assay. Additionally, the observed incidence of antibody (including neutralizing antibody) positivity in an assay may be influenced by several factors including assay methodology, sample handling, timing of sample collection, concomitant medications, and underlying disease. For these reasons, the incidence of antibodies to semaglutide in the studies described below cannot be directly compared with the incidence of antibodies in other studies or to other products. Across the placebo- and active-controlled glycemic control trials, 32 (1.0%) OZEMPIC®-treated patients developed anti-drug antibodies (ADAs) to the active ingredient in OZEMPIC® (i.e., semaglutide). Of the 32 semaglutide-treated patients that developed semaglutide ADAs, 19 patients (0.6% of the overall population) developed antibodies cross-reacting with native GLP-1. The in vitro neutralizing activity of the antibodies is uncertain at this time.

DRUG INTERACTIONS: Concomitant Use with an Insulin Secretagogue (e.g., Sulfonylurea) or with Insulin: The risk of hypoglycemia is increased when OZEMPIC® is used in combination with insulin secretagogues (e.g., sulfonylureas) or insulin. The risk of hypoglycemia may be lowered by a reduction in the dose of sulfonylurea (or other concomitantly administered insulin secretagogues) or insulin *[see Warnings and Precautions]*. **Oral Medications:** OZEMPIC® causes a delay of gastric emptying, and thereby has the potential to impact the absorption of concomitantly administered oral medications. In clinical pharmacology trials, semaglutide did not affect the absorption of orally administered medications to any clinically relevant degree. Nonetheless, caution should be exercised when oral medications are concomitantly administered with OZEMPIC®.

USE IN SPECIFIC POPULATIONS: Pregnancy: Risk Summary: There are limited data with semaglutide use in pregnant women to inform a drug-associated risk for adverse developmental outcomes. There are clinical considerations regarding the risks of poorly controlled diabetes in pregnancy *(see Clinical Considerations)*. Based on animal reproduction studies, there may be potential risks to the fetus from exposure to semaglutide during pregnancy. OZEMPIC® should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. In pregnant rats administered semaglutide during organogenesis, embryofetal mortality, structural abnormalities and alterations to growth occurred at maternal exposures below the maximum recommended human dose (MRHD) based on AUC. In rabbits and cynomolgus monkeys administered semaglutide during organogenesis, early pregnancy losses and structural abnormalities were observed at below the MRHD (rabbit) and ≥5-fold the MRHD (monkey). These findings coincided with a marked maternal body weight loss in both animal species *(see Data)*. The estimated background risk of major birth defects is 6–10% in women with pre-gestational diabetes with an HbA_{1c} >7 and has been reported to be as high as 20–25% in women with a HbA_{1c} >10. 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. Clinical Considerations: *Disease associated maternal and fetal risk:* Poorly controlled diabetes during pregnancy increases the maternal risk for diabetic ketoacidosis, pre-eclampsia, spontaneous abortions, preterm delivery, stillbirth and delivery complications. Poorly controlled diabetes increases the fetal risk for major birth defects, stillbirth, and macrosomia related morbidity. Data: *Animal Data:* In a combined fertility and embryofetal development study in rats, subcutaneous doses of 0.01, 0.03 and 0.09 mg/kg/day (0.1-, 0.4-, and 1.1-fold the MRHD) were administered to males for 4 weeks prior to and throughout mating and to females for 2 weeks prior to mating, and throughout organogenesis to Gestation Day 17. In parental animals, pharmacologically mediated reductions in body weight gain and food consumption were observed at all dose levels. In the offspring, reduced growth and fetuses with visceral (heart blood vessels) and skeletal (cranial bones, vertebra, ribs) abnormalities were observed at the human exposure. In an embryofetal development study in pregnant rabbits, subcutaneous doses of 0.0010, 0.0025 or 0.0075 mg/kg/day (0.03-, 0.3-, and 2.3-fold the MRHD) were administered throughout organogenesis from Gestation Day 6 to 19. Pharmacologically mediated reductions in maternal body weight gain and food consumption were observed at all dose levels. Early pregnancy losses and increased incidences of minor visceral (kidney, liver) and skeletal (sternebra) fetal abnormalities were observed at ≥0.0025 mg/kg/day, at clinically relevant exposures. In an embryofetal development study in pregnant cynomolgus monkeys, subcutaneous doses of 0.015, 0.075, and 0.15 mg/kg twice weekly (1.0-, 5.2-, and 14.9-fold the MRHD) were administered throughout organogenesis, from Gestation Day 16 to 50. Pharmacologically mediated, marked initial maternal body weight loss and reductions in body weight gain and food consumption coincided with the occurrence of sporadic abnormalities (vertebra, sternebra, ribs) at ≥0.075 mg/kg twice weekly (≥5X human exposure). In a pre- and postnatal development study in pregnant cynomolgus monkeys, subcutaneous doses of 0.015, 0.075, and 0.15 mg/kg twice weekly (0.7-, 3.3-, and 7.2-fold the MRHD) were administered from Gestation Day 16 to 140. Pharmacologically mediated marked initial maternal body weight loss and reductions in body weight gain and food consumption coincided with an increase in early pregnancy losses and led to delivery of slightly smaller offspring at ≥0.075 mg/kg twice weekly (≥3X human exposure). **Lactation:** Risk Summary: There are no data on the presence of semaglutide in human milk, the effects on the breastfed infant, or the effects on milk production. Semaglutide was present in the milk of lactating rats, however, due to species-specific differences in lactation physiology, the clinical relevance of these data are not clear *(see Data)*. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for OZEMPIC® and any potential adverse effects on the breastfed infant from OZEMPIC® or from the underlying maternal condition. Data: In lactating rats, semaglutide was detected in milk at levels 3-12 fold lower than in maternal plasma. **Females and Males of Reproductive Potential:** Discontinue OZEMPIC® in women at least 2 months before a planned pregnancy due to the long washout period for semaglutide *[see Use in Specific Populations]*. **Pediatric Use:** Safety and efficacy of OZEMPIC® have not been established in pediatric patients (younger than 18 years). **Geriatric Use:** In the pool of placebo- and active-controlled glycemic control trials, 744 (23.6%) OZEMPIC®-treated patients were 65 years of age and over and 102 OZEMPIC®-treated patients (3.2%) patients were 75 years of age and over. In SUSTAIN 6, the cardiovascular outcome trial, 788 (48.0%) OZEMPIC®-treated patients were 65 years of age and over and 157 OZEMPIC®-treated patients (9.6%) patients were 75 years of age and over. No overall differences in safety or efficacy were detected between these patients and younger patients, but greater sensitivity of some older individuals cannot be ruled out. **Renal Impairment:** No dose adjustment of OZEMPIC® is recommended for patients with renal impairment. In subjects with renal impairment including end-stage renal disease (ESRD), no clinically relevant change in semaglutide pharmacokinetics (PK) was observed. **Hepatic Impairment:** No dose adjustment of OZEMPIC® is recommended for patients with hepatic impairment. In a study in subjects with different degrees of hepatic impairment, no clinically relevant change in semaglutide pharmacokinetics (PK) was observed.

OVERDOSAGE: In the event of overdose, appropriate supportive treatment should be initiated according to the patient's clinical signs and symptoms. A prolonged period of observation and treatment for these symptoms may be necessary, taking into account the long half-life of OZEMPIC® of approximately 1 week.

More detailed information is available upon request.

For information about OZEMPIC® contact: Novo Nordisk Inc., 800 Scudders Mill Road, Plainsboro, NJ 08536, 1-888-693-6742

Date of Issue: December 2017

Version: 1

Manufactured by: Novo Nordisk A/S, DK-2880 Bagsvaerd, Denmark

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PATENT INFORMATION:

http://novonordisk-us.com/patients/products/product-patents.html

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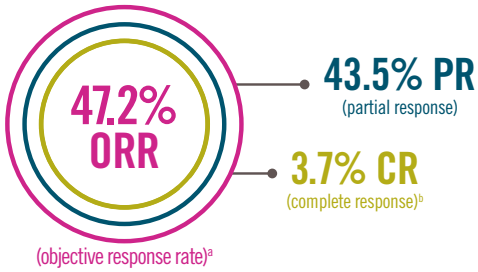
novo nordisk®

OZEMPIC®
semaglutide injection 0.5mg|1mg



A breakthrough for patients with advanced CSCC[1]

LIBTAYO®, a programmed death receptor-1 (PD-1) inhibitor, is the first and only FDA-approved therapy indicated for the treatment of patients with metastatic cutaneous squamous cell carcinoma (CSCC) or locally advanced CSCC who are not candidates for curative surgery or curative radiation[1]



ORR: 51 of 108 patients; 95% confidence interval, 37.5%, 57.1%.[1,2]

61% of responders (31 of 51) reached a duration of response (DoR) of ≥6 months[1,2,a,c]

Median DoR not reached (range: 1-15.2+ months)[1-3,a,c]

[a] At time of data cutoff; based on a combined analysis of Studies 1423 and 1540, which were single-arm, open-label, multicenter, nonrandomized, multicohort studies. Median duration of follow-up was 8.9 months.[1] See additional study design details below.

[b] Only includes patients with complete healing of prior cutaneous involvement; locally advanced CSCC patients in Study 1540 required biopsy to confirm CR.[1]

[c] Group 2 patients (locally advanced CSCC; cemiplimab-rwlc 3 mg/kg every 2 weeks) who started treatment less than 9 months prior to the data cutoff date and all Group 3 patients (metastatic CSCC; cemiplimab-rwlc 350 mg every 3 weeks) from Study 1540 are excluded from the efficacy analysis set.[2]

- **Study 1423** was an open-label, multicenter, nonrandomized, multicohort study that included a total of 26 patients with metastatic CSCC or locally advanced CSCC who were not candidates for curative surgery or curative radiation. Patients received LIBTAYO 3 mg/kg intravenously every 2 weeks for up to 48 weeks. Treatment continued until progression of disease, unacceptable toxicity, or completion of planned treatment.[1]
- **Study 1540**—EMPOWER-CSCC 1—was a global, pivotal, open-label, nonrandomized, multicohort study that included a total of 137 patients with metastatic CSCC or locally advanced CSCC who were not candidates for curative surgery or curative radiation.[1,2,4] Patients received LIBTAYO 3 mg/kg intravenously every 2 weeks for up to 96 weeks or 350 mg LIBTAYO every 3 weeks for up to 54 weeks.[1,3] Treatment continued until progression of disease, unacceptable toxicity, or completion of planned treatment.[1]
- The major efficacy outcome measures were confirmed ORR, as assessed by independent central review (ICR), and ICR-assessed DoR.[1]
- Studies 1423 and 1540 excluded patients with autoimmune disease that required systemic therapy with immunosuppressant agents within 5 years; a history of solid organ transplant; prior treatment with PD-1/programmed death ligand 1 (PD-L1) blocking antibodies or other immune checkpoint inhibitor therapy; infection with HIV, hepatitis B, or hepatitis C; or Eastern Cooperative Oncology Group Performance Status ≥2.[1]
- The recommended dose of LIBTAYO is 350 mg administered as an intravenous infusion over 30 minutes every 3 weeks until disease progression or unacceptable toxicity.[1]

Important Safety Information

Warnings and Precautions

Severe and Fatal Immune-Mediated Adverse Reactions

Immune-mediated adverse reactions, which may be severe or fatal, can occur in any organ system or tissue and usually occur during treatment; however, they can also occur after discontinuation. Early identification and management are essential to ensuring safe use of PD-1–blocking antibodies. Monitor for symptoms and signs of immune-mediated adverse reactions. Evaluate clinical chemistries, including liver tests and thyroid function tests, at baseline and periodically during treatment. Institute medical management promptly to include specialty consultation as appropriate.

In general, withhold LIBTAYO for Grade 3 or 4 and certain Grade 2 immune-mediated adverse reactions. Permanently discontinue LIBTAYO for Grade 4 and certain Grade 3 immune-mediated adverse reactions. For Grade 3 or 4 and certain Grade 2 immune-mediated adverse reactions, administer corticosteroids (1 to 2 mg/kg/day prednisone or equivalent) or other appropriate therapy until improvement to Grade 1 or less followed by a corticosteroid taper over 1 month. Consider administration of other systemic immunosuppressants in patients whose immune-mediated adverse reaction is not controlled with corticosteroids. Institute hormone replacement therapy for endocrinopathies as warranted.

Immune-mediated pneumonitis: Immune-mediated pneumonitis occurred in 2.4% of 534 patients receiving LIBTAYO, including Grade 5 (0.2%), Grade 3 (0.7%), and Grade 2 (1.3%). Pneumonitis led to permanent discontinuation of LIBTAYO in 1.3% of patients. Systemic corticosteroids were required in all patients with pneumonitis, including 85% who received prednisone ≥40 mg/day or equivalent. Pneumonitis resolved in 62% of patients. Withhold LIBTAYO for Grade 2, and permanently discontinue for Grade 3 or 4. Resume in patients with complete or partial resolution (Grade 0 to 1) after corticosteroid taper.

Immune-mediated colitis: Immune-mediated colitis occurred in 0.9% of 534 patients receiving LIBTAYO, including Grade 3 (0.4%) and Grade 2 (0.6%). Colitis led to permanent discontinuation of LIBTAYO in 0.2% of patients. Systemic corticosteroids were required in all patients with colitis, including 60% who received prednisone ≥40 mg/day or equivalent. Colitis resolved in 80% of patients. Withhold LIBTAYO for Grade 2 or 3, and permanently discontinue for Grade 4. Resume in patients with complete or partial resolution (Grade 0 to 1) after corticosteroid taper.

Immune-mediated hepatitis: Immune-mediated hepatitis occurred in 2.1% of 534 patients receiving LIBTAYO, including Grade 5 (0.2%), Grade 4 (0.2%), and Grade 3 (1.7%). Hepatitis led to permanent discontinuation of LIBTAYO in 0.9% of patients. Systemic corticosteroids were required in all patients with hepatitis, including 91% who received prednisone ≥40 mg/day or equivalent. Hepatitis resolved in 64% of patients. Withhold LIBTAYO if AST or ALT increases to more than 3 and up to 10 times the upper limit of normal (ULN) or if total bilirubin increases up to 3 times the ULN. Permanently discontinue LIBTAYO if AST or ALT increases to more than 10 times the ULN or total bilirubin increases to more than 3 times the ULN. Resume in patients with complete or partial resolution (Grade 0 to 1) after corticosteroid taper.

Immune-mediated endocrinopathies: Withhold LIBTAYO if clinically necessary for Grade 2, 3, or 4.

- **Adrenal insufficiency:** Adrenal insufficiency occurred in 0.4% of 534 patients receiving LIBTAYO, including Grade 3 (0.2%) and Grade 2 (0.2%)
- **Hypophysitis:** Hypophysitis, which can result in hypopituitarism, occurred in 0.2% of 534 patients receiving LIBTAYO, which consisted of 1 patient with Grade 3 hypophysitis
- **Hypothyroidism:** Hypothyroidism occurred in 6% of 534 patients receiving LIBTAYO, including Grade 3 (0.2%) and Grade 2 (5.6%); no patients discontinued hormone replacement therapy

Please see additional Important Safety Information and Brief Summary of full Prescribing Information on the following pages.

LIBTAYO demonstrated meaningful tumor reduction in clinical trial patients[1,2]

Partial responses*

These are examples from the 47.2% of patients (43.5% PR,† 3.7% CR‡) who had an objective response (defined as PRs + CRs) in clinical trials. Individual patient responses may vary.

Locally advanced CSCC Not a candidate for curative surgery or curative radiation

History
- 70-year-old male
- Auricular lesions§

Outcomes
- Best overall response: PR per WHO Criteria by independent central review
- Best percent change in target lesion(s): –91.9

Screening | **After 8 weeks** | **After 32 weeks**



Metastatic CSCC

History
- 66-year-old male
- Clavicular lesions

Outcomes
- Best overall response: PR per RECIST 1.1 by independent central review
- Best percent change in target lesion(s): –71.1

Screening | **After 8 weeks** | **After 48 weeks**



*Results as of data cutoff. Group 2 patients (laCSCC; cemiplimab-rwlc 3 mg/kg Q2W) who started treatment less than 9 months prior to the data cutoff date and all Group 3 patients (mCSCC; cemiplimab-rwlc 350 mg Q3W) from Study 1540 are excluded from the efficacy analysis set.[2]

† Partial response is defined as a decrease of 30% or greater in the sum of the diameters of target lesions, taking as reference the baseline sum of diameters, per RECIST 1.1. Partial response of externally visible disease is defined as a decrease of 50% or greater in the sum of products of perpendicular longest dimensions of target lesions, per WHO Criteria. Responses had to be maintained for at least 4 weeks.[2]

‡ Complete response is defined as disappearance of all target lesions for at least 4 weeks. Only includes patients with complete healing of prior cutaneous involvement; locally advanced CSCC patients in Study 1540 required biopsy to confirm CR.[1,2]

§ This patient also had cranial lesions that were included in the calculation of best percent change in target lesion(s). Those images are not included here.[2]

laCSCC, locally advanced cutaneous squamous cell carcinoma; mCSCC, metastatic cutaneous squamous cell carcinoma; Q2W, every 2 weeks; Q3W, every 3 weeks; RECIST, Response Evaluation Criteria in Solid Tumors; WHO, World Health Organization.

See more patient profiles at LIBTAYOhcp.com.

Important Safety Information

Warnings and Precautions

Severe and Fatal Immune-Mediated Adverse Reactions

Immune-mediated endocrinopathies (continued):

- **Hyperthyroidism:** Hyperthyroidism occurred in 1.5% of 534 patients receiving LIBTAYO, including Grade 3 (0.2%) and Grade 2 (0.4%); hyperthyroidism resolved in 38% of patients
- **Type 1 diabetes mellitus:** Type 1 diabetes mellitus, which can present with diabetic ketoacidosis, occurred in 0.7% of 534 patients, including Grade 4 (0.4%) and Grade 3 (0.4%); type 1 diabetes mellitus led to permanent discontinuation of LIBTAYO in 0.2% of patients

Immune-mediated nephritis with renal dysfunction: Immune-mediated nephritis occurred in 0.6% of 534 patients receiving LIBTAYO, including Grade 3 (0.4%) and Grade 2 (0.2%). Nephritis led to permanent discontinuation of LIBTAYO in 0.2% of patients. Systemic corticosteroids were required in all patients with nephritis, including 67% who received prednisone ≥40 mg/day or equivalent. Nephritis resolved in all patients. Withhold LIBTAYO for Grade 3, and permanently discontinue for Grade 4. Resume in patients with complete or partial resolution (Grade 0 to 1) after corticosteroid taper.

Immune-mediated dermatologic adverse reactions: Immune-mediated dermatologic reactions, including erythema multiforme and pemphigoid, occurred in 1.7% of 534 patients receiving LIBTAYO, including Grade 3 (1.1%) and Grade 2 (0.6%). In addition, SJS and TEN have been observed with LIBTAYO and with other products in this class. Systemic corticosteroids were required in all patients with dermatologic reactions, including 89% who received prednisone ≥40 mg/day or equivalent. Dermatologic reactions resolved in 33% of patients. Approximately 22% of patients had recurrence of dermatologic reactions after re-initiation of LIBTAYO. Withhold LIBTAYO for Grade 3, and permanently discontinue for Grade 4. Resume in patients with complete or partial resolution (Grade 0 to 1) after corticosteroid taper.

Other immune-mediated adverse reactions: The following clinically significant immune-mediated adverse reactions occurred at an incidence of <1% in 534 patients who received LIBTAYO or were reported with the use of other PD-1–blocking and PD-L1–blocking antibodies. Severe or fatal cases have been reported for some of these adverse reactions. Withhold LIBTAYO for Grade 3, and permanently discontinue for Grade 4. Resume in patients with complete or partial resolution (Grade 0 to 1) after corticosteroid taper.

- **Neurological:** Meningitis, encephalitis, myelitis and demyelination, myasthenic syndrome/myasthenia gravis, Guillain-Barré syndrome, nerve paresis, and autoimmune neuropathy
- **Cardiovascular:** Myocarditis, pericarditis, and vasculitides
- **Ocular:** Uveitis, iritis, and other ocular inflammatory toxicities. Some cases can be associated with retinal detachment. Various Grades of visual impairment to include blindness can occur. If uveitis occurs in combination with other immune-mediated adverse reactions, consider a Vogt-Koyanagi-Harada–like syndrome, as this may require treatment with systemic corticosteroids to reduce the risk of permanent vision loss
- **Gastrointestinal:** Pancreatitis to include increases in serum amylase and lipase levels, gastritis, and duodenitis
- **Musculoskeletal and connective tissue:** Myositis, rhabdomyolysis, and associated sequelae, including renal failure, arthritis, and polymyalgia rheumatica
- **Hematological and immunological:** Hemolytic anemia, aplastic anemia, hemophagocytic lymphohistiocytosis, systemic inflammatory response syndrome, histiocytic necrotizing lymphadenitis (Kikuchi lymphadenitis), sarcoidosis, immune thrombocytopenic purpura, and solid organ transplant rejection

Infusion-related reactions

Severe infusion-related reactions (Grade 3) occurred in 0.2% of patients receiving LIBTAYO. Monitor patients for signs and symptoms of infusion-related reactions. Interrupt or slow the rate of infusion for Grade 1 or 2, and permanently discontinue for Grade 3 or 4.

Embryo-fetal toxicity

LIBTAYO can cause fetal harm when administered to a pregnant woman due to an increased risk of immune-mediated rejection of the developing fetus resulting in fetal death. Advise women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with LIBTAYO and for at least 4 months after the last dose.

Adverse reactions

- Serious adverse reactions occurred in 28% of patients. Serious adverse reactions that occurred in ≥2% of patients were cellulitis, sepsis, pneumonia, pneumonitis, and urinary tract infection. The most common Grade 3-4 adverse reactions (≥2%) were cellulitis, sepsis, hypertension, pneumonia, musculoskeletal pain, skin infection, urinary tract infection, and fatigue
- LIBTAYO was permanently discontinued due to adverse reactions in 5% of patients; adverse reactions resulting in permanent discontinuation were pneumonitis, autoimmune myocarditis, hepatitis, aseptic meningitis, complex regional pain syndrome, cough, and muscular weakness
- The most common adverse reactions (incidence ≥20%) were fatigue, rash, and diarrhea

Use in specific populations

- **Lactation:** Because of the potential for serious adverse reactions in breastfed children, advise women not to breastfeed during treatment and for at least 4 months after the last dose of LIBTAYO
- **Females and males of reproductive potential:** Verify pregnancy status in females of reproductive potential prior to initiating LIBTAYO

Please see Brief Summary of full Prescribing Information on the following page.

References: 1. LIBTAYO (cemiplimab-rwlc) injection full U.S. prescribing information. Regeneron Pharmaceuticals, Inc., and sanofi-aventis U.S. LLC. **2.** Data on file. Regeneron Pharmaceuticals Inc. **3.** Migden MR et al. *N Engl J Med.* 2018;379(4):341-351. **4.** Study of REGN2810 in patients with advanced cutaneous squamous cell carcinoma. Clinicaltrials.gov. https://clinicaltrials.gov/ct2/show/study/NCT02760498. Published May 3, 2016. Updated January 14, 2019. Accessed June 10, 2019.

To learn more about LIBTAYO, speak with your sales representative or visit LIBTAYOhcp.com.

REGENERON | SANOFI GENZYME

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LIBTAYO®
(cemiplimab-rwlc)
Injection 350 mg

LIBTAYO® (cemiplimab-rwlc) injection, for intravenous use

Brief Summary of Prescribing Information

1 INDICATIONS AND USAGE

LIBTAYO is indicated for the treatment of patients with metastatic cutaneous squamous cell carcinoma (CSCC) or locally advanced CSCC who are not candidates for curative surgery or curative radiation.

4 CONTRAINDICATIONS

None.

5 WARNINGS AND PRECAUTIONS

5.1 Severe and Fatal Immune-Mediated Adverse Reactions

LIBTAYO is a monoclonal antibody that belongs to a class of drugs that binds to the programmed death receptor-1 (PD-1), blocking the PD-1/PD-L1 pathway, thereby removing inhibition of the immune response with the potential for breaking of peripheral tolerance and induction of immune-mediated adverse reactions. Important immune-mediated adverse reactions listed under Warnings and Precautions may not be inclusive of all possible immune-mediated reactions.

Immune-mediated adverse reactions, which may be severe or fatal, can occur in any organ system or tissue. While immune-mediated adverse reactions usually manifest during treatment with PD-1/PD-L1 blocking antibodies, immune-mediated adverse reactions can also manifest after discontinuation of PD-1/PD-L1 blocking antibodies.

Early identification and management are essential to ensure safe use of PD-1/PD-L1 blocking antibodies. Monitor for symptoms and signs of immune-mediated adverse reactions. Evaluate clinical chemistries, including liver tests and thyroid function tests, at baseline and periodically during treatment. Institute medical management promptly to include specialty consultation as appropriate.

In general, withhold LIBTAYO for Grade 3 or 4 and certain Grade 2 immune-mediated adverse reactions. Permanently discontinue LIBTAYO for Grade 4 and certain Grade 3 immune-mediated adverse reactions *[see Dosage and Administration (2.2)]*. For Grade 3 or 4 and certain Grade 2 immune-mediated adverse reactions, administer corticosteroids (1 to 2 mg/kg/day prednisone or equivalent) or other appropriate therapy until improvement to Grade 1 or less followed by a corticosteroid taper over one month *[see Dosage and Administration (2.2)]*. Consider administration of other systemic immunosuppressants in patients whose immune-mediated adverse reaction is not controlled with corticosteroids. Institute hormone replacement therapy for endocrinopathies as warranted.

Immune-Mediated Pneumonitis

Immune-mediated pneumonitis occurred in 2.4% of 534 patients receiving LIBTAYO, including Grade 5 (0.2%), Grade 3 (0.7%) and Grade 2 (1.3%) *[see Adverse Reactions (6.1)]*. Pneumonitis led to permanent discontinuation of LIBTAYO in 1.3% of patients. Systemic corticosteroids were required in all patients with pneumonitis, including 85% who received prednisone ≥40 mg per day or equivalent. Pneumonitis resolved in 62% of patients.

Immune-Mediated Colitis

Immune-mediated colitis occurred in 0.9% of 534 patients receiving LIBTAYO, including Grade 3 (0.4%) and Grade 2 (0.6%) *[see Adverse Reactions (6.1)]*. Colitis led to permanent discontinuation of LIBTAYO in 0.2% of patients. Systemic corticosteroids were required in all patients with colitis, including 60% who received prednisone ≥40 mg per day or equivalent. Colitis resolved in 80% of patients.

Immune-Mediated Hepatitis

Immune-mediated hepatitis occurred in 2.1% of 534 patients receiving LIBTAYO, including Grade 5 (0.2%), Grade 4 (0.2%), and Grade 3 (1.7%) *[see Adverse Reactions (6.1)]*. Hepatitis led to permanent discontinuation of LIBTAYO in 0.9% of patients. Systemic corticosteroids were required in all patients with hepatitis, including 91% who received prednisone ≥40 mg per day or equivalent. Hepatitis resolved in 64% of patients.

Immune-Mediated Endocrinopathies

Adrenal Insufficiency

Adrenal insufficiency occurred in 0.4% of 534 patients receiving LIBTAYO, including Grade 3 (0.2%), and Grade 2 (0.2%) *[see Adverse Reactions (6.1)]*.

Hypophysitis

Hypophysitis, which can result in hypopituitarism, occurred in 0.2% of 534 patients receiving LIBTAYO, which consisted of one patient with Grade 3 hypophysitis.

Hypothyroidism

Hypothyroidism occurred in 6% of 534 patients receiving LIBTAYO, including Grade 3 (0.2%) and Grade 2 (5.6%). No patients discontinued hormone replacement therapy.

Hyperthyroidism

Hyperthyroidism occurred in 1.5% of 534 patients receiving LIBTAYO, including Grade 3 (0.2%) and Grade 2 (0.4%). Hyperthyroidism resolved in 38% of patients.

Type 1 Diabetes Mellitus

Type 1 diabetes mellitus, which can present with diabetic ketoacidosis, occurred in 0.7% of 534 patients, including Grade 4 (0.4%) and Grade 3 (0.4%). Type 1 diabetes mellitus led to permanent discontinuation of LIBTAYO in 0.2% of patients.

Immune-Mediated Nephritis with Renal Dysfunction

Immune-mediated nephritis occurred in 0.6% of 534 patients receiving LIBTAYO, including Grade 3 (0.4%) and Grade 2 (0.2%) *[see Adverse Reactions (6.1)]*. Nephritis led to permanent discontinuation of LIBTAYO in 0.2% of patients. Systemic corticosteroids were required in all patients with nephritis, including 67% who received prednisone ≥40 mg per day or equivalent. Nephritis resolved in all patients.

Immune-Mediated Dermatologic Adverse Reactions

Immune-mediated dermatologic reactions, including erythema multiforme and pemphigoid, occurred in 1.7% of 534 patients receiving LIBTAYO, including Grade 3 (1.1%) and Grade 2 (0.6%) *[see Adverse Reactions (6.1)]*. In addition, SJS and TEN have been observed with LIBTAYO and with other products in this class. Systemic corticosteroids were required in all patients with dermatologic reactions, including 89% who received prednisone ≥40 mg per day or equivalent. Dermatologic reactions resolved in 33% of patients. Approximately 22% of patients had recurrence of dermatologic reactions after re-initiation of LIBTAYO.

Other Immune-Mediated Adverse Reactions

The following clinically significant immune-mediated adverse reactions occurred at an incidence of <1% in 534 patients who received LIBTAYO *[see Adverse Reactions (6.1)]* or were reported with the use of other PD-1/PD-L1 blocking antibodies. Severe or fatal cases have been reported for some of these adverse reactions.

Neurological: Meningitis, encephalitis, myelitis and demyelination, myasthenic syndrome / myasthenia gravis, Guillain-Barre syndrome, nerve paresis, autoimmune neuropathy

Cardiovascular: Myocarditis, pericarditis, vasculitides

Ocular: Uveitis, iritis, and other ocular inflammatory toxicities. Some cases can be associated with retinal detachment. Various grades of visual impairment to include blindness can occur. If uveitis occurs in combination with other immune-mediated adverse reactions, consider a Vogt-Koyanagi-Harada like syndrome, as this may require treatment with systemic corticosteroids to reduce the risk of permanent vision loss.

Gastrointestinal: Pancreatitis to include increases in serum amylase and lipase levels, gastritis, duodenitis

Musculoskeletal and Connective Tissue: Myositis, rhabdomyolysis and associated sequelae including renal failure, arthritis, polymyalgia rheumatica

Hematological and Immunological: Hemolytic anemia, aplastic anemia, hemophagocytic lymphohistiocytosis, systemic inflammatory response syndrome, histiocytic necrotizing lymphadenitis (Kikuchi lymphadenitis), sarcoidosis, immune thrombocytopenic purpura, solid organ transplant rejection

5.2 Infusion-Related Reactions

Severe infusion-related reactions (Grade 3) occurred in 0.2% of patients receiving LIBTAYO *[see Adverse Reactions (6.1)]*. Monitor patients for signs and symptoms of infusion-related reactions. Interrupt or slow the rate of infusion or permanently discontinue LIBTAYO based on severity of reaction *[see Dosage and Administration (2.2)]*.

5.3 Embryo-Fetal Toxicity

Based on its mechanism of action, LIBTAYO can cause fetal harm when administered to a pregnant woman. Animal studies have demonstrated that inhibition of the PD-1/PD-L1 pathway can lead to increased risk of immune-mediated rejection of the developing fetus resulting in fetal death. Advise women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with LIBTAYO and for at least 4 months after the last dose *[see Use in Specific Populations (8.1, 8.3)]*.

6 ADVERSE REACTIONS

The following serious adverse reactions are described elsewhere in the labeling.

- Severe and Fatal Immune-Mediated Adverse Reactions *[see Warnings and Precautions (5.1)]*
- Infusion-Related Reactions *[see Warnings and Precautions (5.2)]*

6.1 Clinical Trials Experience

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

The data described in WARNINGS AND PRECAUTIONS reflect exposure to LIBTAYO in 534 patients in two open-label, single-arm, multicohort studies (Study 1423 and Study 1540), including 98 patients with metastatic (nodal or distant) CSCC, 65 patients with locally advanced CSCC, and 371 patients with other advanced solid tumors. LIBTAYO as a single agent or in combination with chemotherapy or radiation was administered intravenously at doses of 1 mg/kg every 2 weeks (n=27), 3 mg/kg every 2 weeks (n=446), 3 mg/kg every 3 weeks (n=12), 10 mg/kg every 2 weeks (n=6), 200 mg every 2 weeks (n=20) or 350 mg every 3 weeks (n=23). Among the 534 patients, 38% were exposed for ≥6 months and 16% were exposed for ≥12 months.

The data described below reflect exposure to LIBTAYO in 163 patients with advanced CSCC (metastatic or locally advanced disease) in Study 1423 and Study 1540. Patients received LIBTAYO 1 mg/kg every 2 weeks (n=1), 3 mg/kg every 2 weeks (n=139) or 350 mg every 3 weeks (n=23) as an intravenous infusion until disease progression, unacceptable toxicity, or completion of planned treatment. The median duration of exposure was 20 weeks (3 days to 1.4 years).

The safety population characteristics were: median age of 71 years (38 to 96 years), 85% male, 96% white, and ECOG performance score (PS) of 0 (44%) or 1 (56%).

The most common adverse reactions reported in at least 20% of patients were fatigue, rash and diarrhea. The most common Grade 3-4 adverse reactions (≥2%) were cellulitis, sepsis, hypertension, pneumonia, musculoskeletal pain, skin infection, urinary tract infection and fatigue. LIBTAYO was permanently discontinued due to adverse reactions in 5% of patients; adverse reactions resulting in permanent discontinuation were pneumonitis, autoimmune myocarditis, hepatitis, aseptic meningitis, complex regional pain syndrome, cough, and muscular weakness. Serious adverse reactions occurred in 28% of patients. Serious adverse reactions that occurred in at least 2% of patients were cellulitis, sepsis, pneumonia, pneumonitis and urinary tract infection.

Table 1 summarizes the adverse reactions that occurred in ≥10% of patients and Table 2 summarizes Grade 3 and 4 laboratory abnormalities worsening from baseline in ≥1% of patients receiving LIBTAYO.

Table 1: Adverse Reactions in ≥10% of Patients with Advanced CSCC Receiving LIBTAYO in Study 1423 and Study 1540

Adverse Reactions	LIBTAYO N=163	
	All Grades %	Grade 3-4 %
Skin and Subcutaneous Tissue		
Rash*	25	1.2
Pruritus†	15	0
Gastrointestinal		
Diarrhea‡	22	0.6
Nausea	19	0
Constipation	12	0.6
General and Administration Site		
Fatigue§	29	2
Musculoskeletal and Connective Tissue		
Musculoskeletal pain#	17	3
Metabolism and Nutrition		
Decreased appetite	10	0

* Rash is a composite term that includes rash maculopapular, rash, dermatitis, rash generalized, dermatitis bullous, drug eruption, erythema, rash erythematous, rash macular, rash pruritic, and skin reaction.
† Pruritus is a composite term that includes pruritus and pruritus allergic.
‡ Diarrhea is a composite term that includes diarrhea and colitis.
§ Fatigue is a composite term that includes fatigue and asthenia.
# Musculoskeletal pain is a composite term that includes: musculoskeletal pain, back pain, myalgia, neck pain, pain in extremity.

Table 2: Grade 3 or 4 Laboratory Abnormalities Worsening from Baseline in ≥1% of Patients with Advanced CSCC Receiving LIBTAYO in Study 1423 and Study 1540

Laboratory Abnormality	Grade 3-4 (%)†
Chemistry	
Increased aspartate aminotransferase	3
Increased INR	2
Hypoalbuminemia	1
Hematology	
Lymphopenia	7
Anemia	2
Electrolytes	
Hypophosphatemia	4
Hyponatremia	3
Hypercalcemia	1

† Percentages are based on the number of patients with at least 1 post-baseline value available for that parameter.

6.2 Immunogenicity

As with all therapeutic proteins, there is a potential for immunogenicity. The detection of antibody formation is highly dependent on the sensitivity and specificity of the assay. Additionally, the observed incidence of antibody (including neutralizing antibody) positivity in an assay may be influenced by several factors including assay methodology, sample handling, timing of sample collection, concomitant medications, and underlying disease. For these reasons, comparison of the incidence of antibodies to cemiplimab-rwlc in the studies described below with the incidence of antibodies in other studies or to other products may be misleading.

Anti-drug antibodies (ADA) were tested in 398 of 534 patients who received LIBTAYO and the incidence of cemiplimab-rwlc treatment-emergent ADAs was 1.3% using an electrochemiluminescent (ECL) bridging immunoassay; 0.3% were persistent ADA responses. In the patients who developed anti-cemiplimab-rwlc antibodies, there was no evidence of an altered pharmacokinetic profile of cemiplimab-rwlc.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

Based on its mechanism of action, LIBTAYO can cause fetal harm when administered to a pregnant woman. There are no available data on the use of LIBTAYO in pregnant women. Animal studies have demonstrated that inhibition of the PD-1/PD-L1 pathway can lead to increased risk of immune-mediated rejection of the developing fetus resulting in fetal death *(see Data)*. Human IgG4 immunoglobulins (IgG4) are known to cross the placenta; therefore, LIBTAYO has the potential to be transmitted from the mother to the developing fetus. Advise women of the potential risk to a fetus.

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

Data

Animal Data

Animal reproduction studies have not been conducted with LIBTAYO to evaluate its effect on reproduction and fetal development. A central function of the PD-1/PD-L1 pathway is to preserve pregnancy by maintaining maternal immune tolerance to the fetus. In murine models of pregnancy, blockade of PD-L1 signaling has been shown to disrupt tolerance to the fetus and to result in an increase in fetal loss; therefore, potential risks of administering LIBTAYO during pregnancy include increased rates of abortion or stillbirth. As reported in the literature, there were no malformations related to the blockade of PD-1/PD-L1 signaling in the offspring of these animals; however, immune-mediated disorders occurred in PD-1 and PD-L1 knockout mice. Based on its mechanism of action, fetal exposure to cemiplimab-rwlc may increase the risk of developing immune-mediated disorders or altering the normal immune response.

8.2 Lactation

Risk Summary

There is no information regarding the presence of cemiplimab-rwlc in human milk, or its effects on the breastfed child or on milk production. Because of the potential for serious adverse reactions in breastfed children, advise women not to breastfeed during treatment and for at least 4 months after the last dose of LIBTAYO.

8.3 Females and Males of Reproductive Potential

Pregnancy Testing

Verify pregnancy status in females of reproductive potential prior to initiating LIBTAYO *[see Use in Specific Populations (8.1)]*.

Contraception

LIBTAYO can cause fetal harm when administered to a pregnant woman *[see Use in Specific Populations (8.1)]*.

Females

Advise females of reproductive potential to use effective contraception during treatment with LIBTAYO and for at least 4 months after the last dose.

8.4 Pediatric Use

The safety and effectiveness of LIBTAYO have not been established in pediatric patients.

8.5 Geriatric Use

Of the 163 patients with metastatic and locally advanced CSCC who received LIBTAYO in clinical studies, 72% were 65 years or older and 37% were 75 years or older. No overall differences in safety or effectiveness were observed between these subjects and younger subjects.

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US-LIB-1510 04/19

4 WAYS TO START IMMEDIATELY INCREASING REVENUE



1 ANS TESTING (can be combined with SUDOMOTOR into 1 full system)

- Takes less than 10 minutes to perform, software provides verbal cues
- Tests for autonomic balance, vascular health, physical/mental stress, peripheral nerve health and other critical hidden risk factors
- Reimburses $170/test using 3 CPT codes
- Provides a 1 page summary up to a full 24 page comprehensive report

7857



2 SUDOMOTOR TESTING (can be combined with ANS into 1 full system)

- Takes 3 minutes to analyze a patients' hands and feet
- Provides a 1 page summary report
- Assesses peripheral nerve health (c-fiber function) and asymmetry between each hand and foot
- Reimburses $130/test (national average)

7858



3 ALLERGY TESTING

- Turn Key, comprehensive system
- 80-panel test, NO HIGH RISK (shellfish/peanuts/berries)
- 2 Minutes to apply, 15 minutes to show results
- Reimburses average $270 - $350/test, costs ~ $100/test (antigens/applicators)
- Options for Immunotherapy Treatment

7859



4 NEURO-COGNITIVE TESTING

- Medicare mandates yearly cognitive assessment
- Takes 10-15 minutes to prep patient, 20 minutes to test
- Analyzes: brain health (EEG), brain processing speed (Evoke Potentials), heart health (EKG), mental health (neuropsychology)
- Reimburses using 6 CPT codes, National Average = $750 - $1000 per test
- Each test is processed into a fully-finished, clinically actionable report
- Easy to understand biomarkers facilitate more informed medical interventions, such as biofeedback

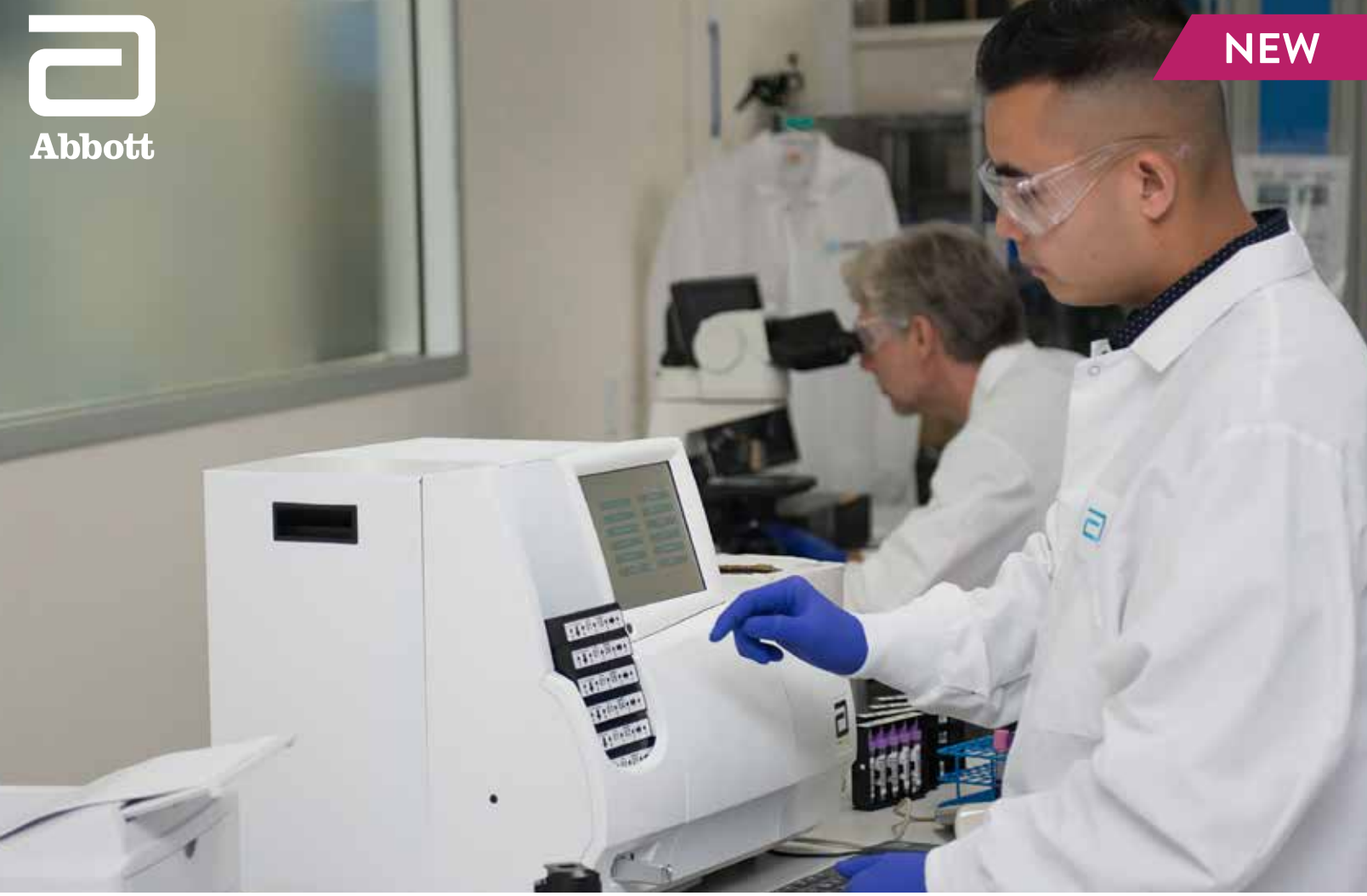
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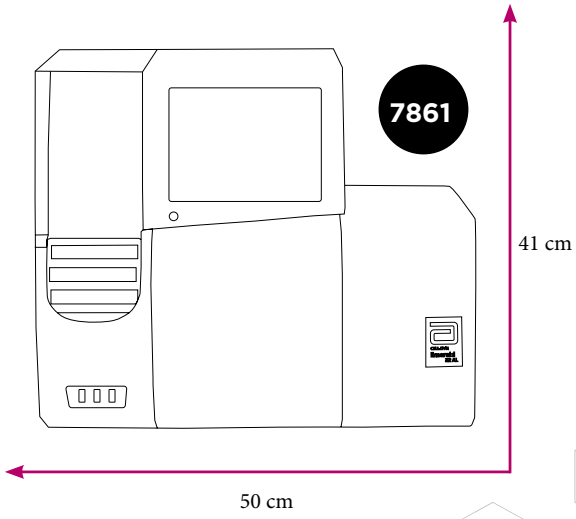
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