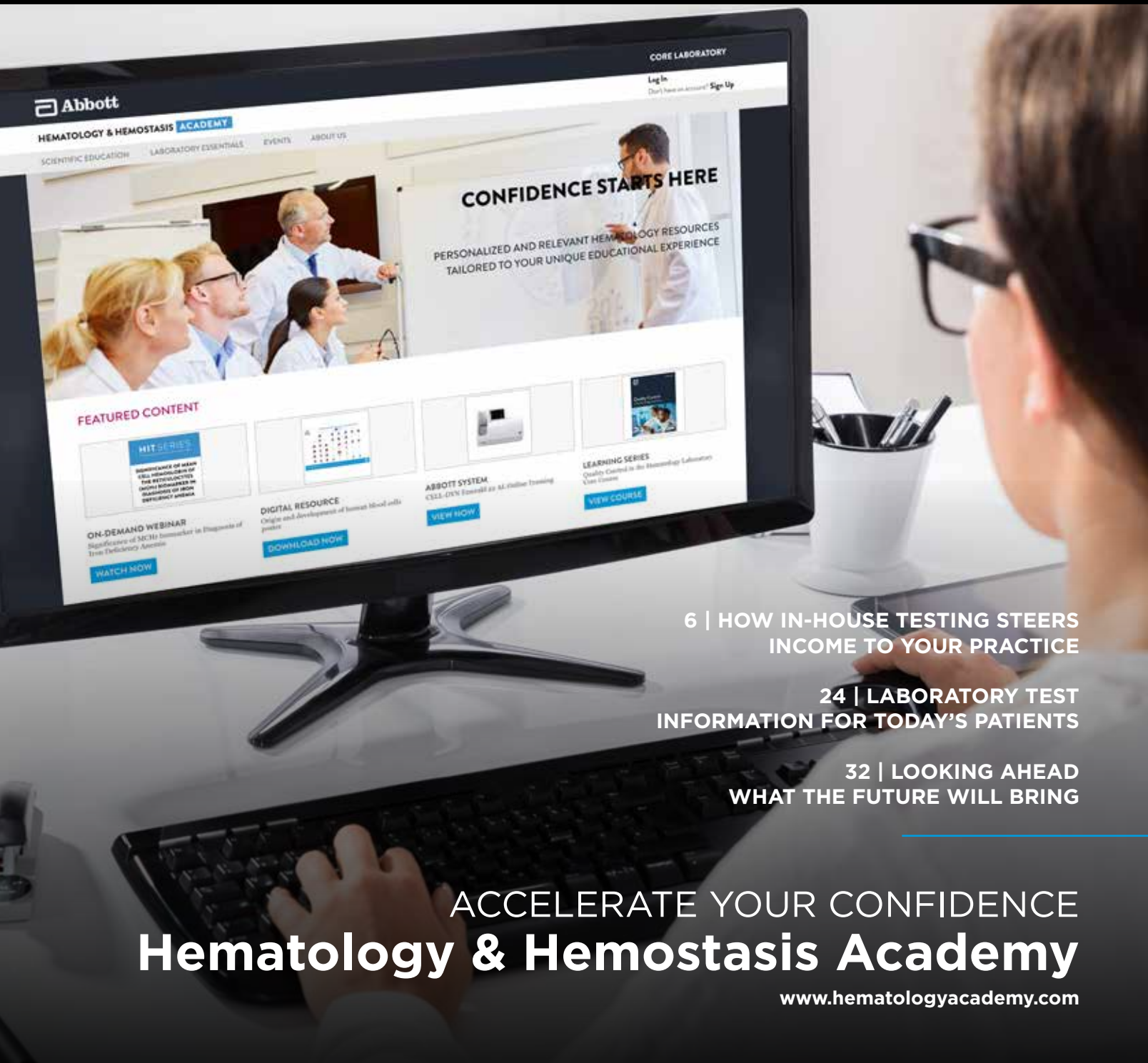
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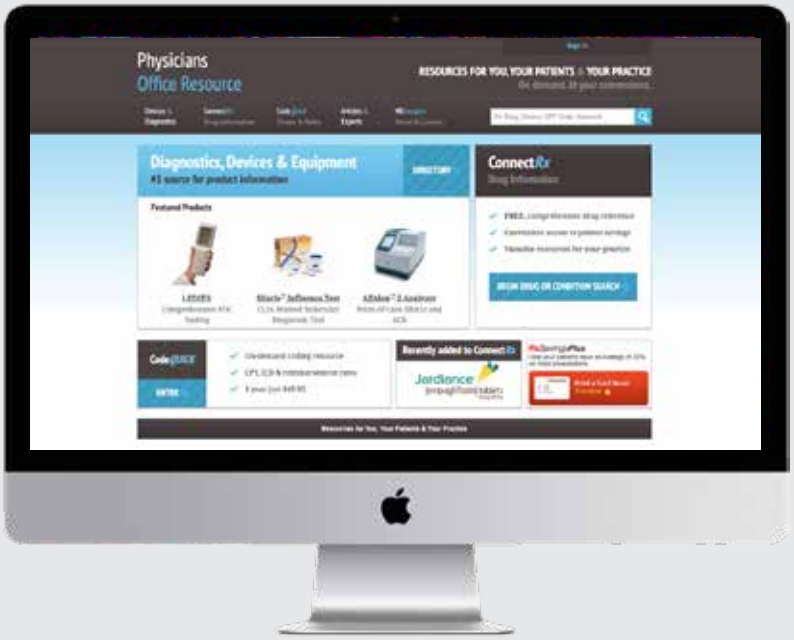


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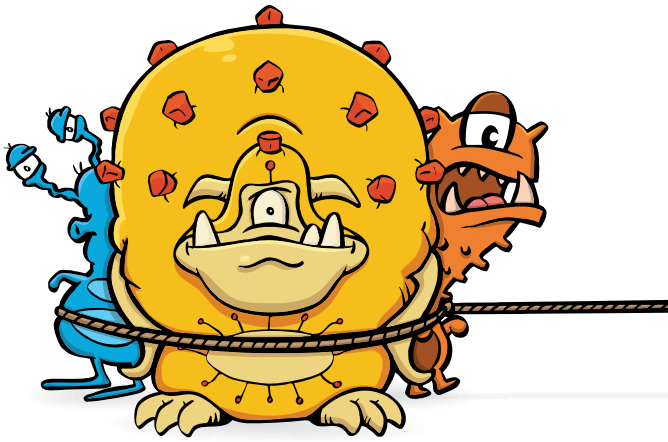
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2. For use with the CLIA-waived BioFire® FilmArray® 2.0 EZ configuration.

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HOW IN-HOUSE TESTING STEERS INCOME TO YOUR PRACTICE

BY DYLAN J. CHADWICK

We all laughed at Casey, bright-eyed and eager, when we started our hike. He'd seemingly bought out an entire military surplus store in preparation, while we'd opted (through a heady combination of laziness and daring) to pack as little as possible. Most curiously was Casey's hand-pump micron water filter. Roughly the size of a cinder-block and forged from heavy metal, we snorted incredulously as he clipped the device to his pack, hiked up his shorts and started his journey, clattering like an old Buick.

However, hiking a 70 mile swatch of the Appalachian trail proved more treacherous than we'd imagined, and as the sweltering humidity of the Tennessee backwoods enveloped us, the need for water grew to maddening levels. The iodine tablets we'd packed tasted too strongly of paint, rendering anything we put them in practically undrinkable and our "fool-proof" method of boiling water to purify it took way too long. In a moment of parched desperation, we turned to Casey, sitting cross-legged on an old stump, patiently pumping ice-cold potable water into his canteen. Sheepishly, we approached him for help. "Sure," he replied with a grin. "I ought to charge you though." It occurred to me, there in the Appalachian wilderness, that Casey had taken the time to specialize, and despite the additional weight and effort his equipment entailed, he now had what we all wanted...and was poised to make a killing.

Similarly, in a changing medical landscape, physicians willing to specialize their practices are the ones who'll succeed. Though evolving technology and its subsequent improvements in patient patient care have brought substantial changes to the medical sector, an era of economic uncertainty and fiscal instability may wring just as prescient an effect. According to an article by Ben Brown, MD, reductions in Medicare contract payments (some as much as 21.3%) and physician reimbursements from insurers might result in critical decreases in physician salaries, medical profits and general revenue for a practice. What proves even more concerning for physicians and patients alike, is a present medical landscape of high healthcare costs, an ever-increasing need for healthcare options and diminishing resources. Furthermore, caring physicians want to be effective providers for their patients, but they also want the appreciation and financial compensation for their profession demands.

In this regard, many physicians, Urologists, Oncologists, Gastroenterologists and Dermatologists for example, have made conscious efforts to optimize their practices in an effort to generate other streams of ancillary income. One specializing measure has been opening in-office testing labs (POL's) directly at their office location. These labs, carefully stocked and equipped to run routine (but important) procedural tests, provide real life "one stop shop" scenarios for patients with busy schedules



and limited funds, and can quickly develop into thriving profit centers for small practices...but before opening up a lab, let's talk some basics.

Physicians have a number of options when it comes to medical testing. The first, and least efficient, is for them to refer patients to a hospital or an off-site lab for their tests. This method, though convenient for practices with a high volume of appointments, generally proves inconvenient for the patient, who has to make a additional trips for a singular medical problem. Additionally, it yields a low (virtually non-existent) financial return for the physician.

Another "off-site testing" option for physicians is to take the samples in the office, and then send them to an off-site lab for analysis. Commercial Reference Labs (CRL), like Quest Diagnostics, Laboratory Corporation of America Holdings and Bio-Reference Medical Labs, have carved a space in physician circles as adept facilities that aid practices by doing the testing work for them. Still, the method is not without its downsides as it creates another process "step" for physicians who must take the test samples in-house, and then send them off-site before a further diagnosis can be made. Turn-around times increase as patients and physicians wait for their samples, shipping expenses must be considered and again, since Commercial Reference Labs are compensated for their lab work, financial returns for the actual physician are low.

In the immediate sphere, these off-site methods may take stones from practices' proverbial backpack as they're "freed up" to see more patients, but in more pressing ways they're potentially yanking dollars from a practice's proverbial wallet.

A viable route for physicians is to run the testing themselves using products that have been specifically waived by the Clinical Laboratory Improvement Amendments (CLIA). Established in 1988, the CLIA sets standards and issues certifications for clinical laboratory testing, with an emphasis on ensuring accuracy, reliability and timeliness. Using CLIA waived products keeps the testing in-house, and can generate much-needed revenue for a physician by steering testing and procedural fees directly to the practice. However, testing done on CLIA waived products isn't always the most extensive and can be limited in scope.

In an efforts to generate additional income for their practice, and to creating an efficient and all-encompassing experience for their patients, physicians may be better advised not to stop simply at CLIA products, but to establish an entire CLIA certified lab in their office.

In his article Oncologists Advised to Build Their Own In-Office Clinical Labs Michael McBride cites an anecdote by Tim Dumas, a lab scientist and POL consultant, when he says "someone's going to run and get paid for these tests. It might as well be you." In the article, Dumas references a three doctor Oncology practice in Raleigh North Carolina that generates an additional $400,000 annually with their own Physician office lab. He even predicts that a ten to twelve doctor practice can look at $7-800,000 a year in additional revenue if they implement such a facility.

Besides the extra cash flow, in-house Physician Office Labs usher in various benefits for small and mid-level practices. For one, waiting games and turn around time between specimen collection, analysis and patient follow up are diminished. Since tests don't need to be sent out, appointment is maximized and the practice becomes more beneficial both to the patient and to the physician.

Besides adopting the role of a pratice's lucrative profit center, Physician's office labs will help practices save money. Tim Dumas goes as far as to accuse practices of "wasting revenue" when they "decide not to install their own Physician's office lab." He contends that a practice can save anywhere from $100,000 to $1 million (depending on the size) simply by the cut expenses that an in-house lab espouses.

That's not to say that establishing an in-house Physician's Office Lab doesn't have its own set of costs that a practice must take into account. For one, it will require a CLIA certification (approximately $1,200). Depending on the type of practice, it will also require specialized equipment and a space in which to house it. Physicians must make their own decision whether to purchase equipment or to lease it, but Dumas insists that leasing it is cheap and cost effective. Finally, a well-oiled Physician's office lab requires a competent staff of specially trained individuals (the number depends on the size of the lab) and a competent medical lab manager (approximate salary of $75,000 a year) to oversee the testing.

Though hefty, they're necessary expenses and serve multiple worthwhile purposes. For one, specialized staff ensures accuracy and efficiency in testing, and a CLIA certification will protect practices from any legal red tape. Additionally, by putting concentrated amounts of time, effort and resources into their Physician's Office Lab, practices make their lab more attractive to managed care organizations (MCOs) and insurance companies. Subsequently, these organizations are far more likely to give generous reimbursements when they're assured that a POL promotes customer satisfaction, emphasizes quality and generally has effectiveness and efficiency in their top priority.

While many physicians might seek to avoid what Michael Sanders MD calls the "headache" of dealing with CLIA, MCOs and the insurance companies, a top notch Physician's office lab has far more advantages than it does hindrances, and the financial benefits far outweigh the expenses. For example, a standard CBC test for an oncology practice usually costs around $1 to run, but the insruance reimbursement is around $10. After deducting the fixed costs of the lab, profits become substantial, even more so for tests like CEA, CA 125 and CA 27-29 which cost between $3-4 to run and receive insurance reimbursements of $20-30 each.

From simplifying the overall patient experience to whipping together an ancillary stream of income for a practice, it's win-win on all counts. "A practice is at its most efficient, when it's generating revenue," says Tim Dumas. Though it will take effort to get started, the returns will come quickly and practices will come upon their destination, be it financial success, an increase in disposable revenue or a better patient experience, much quicker and more seamlessly with one than without.

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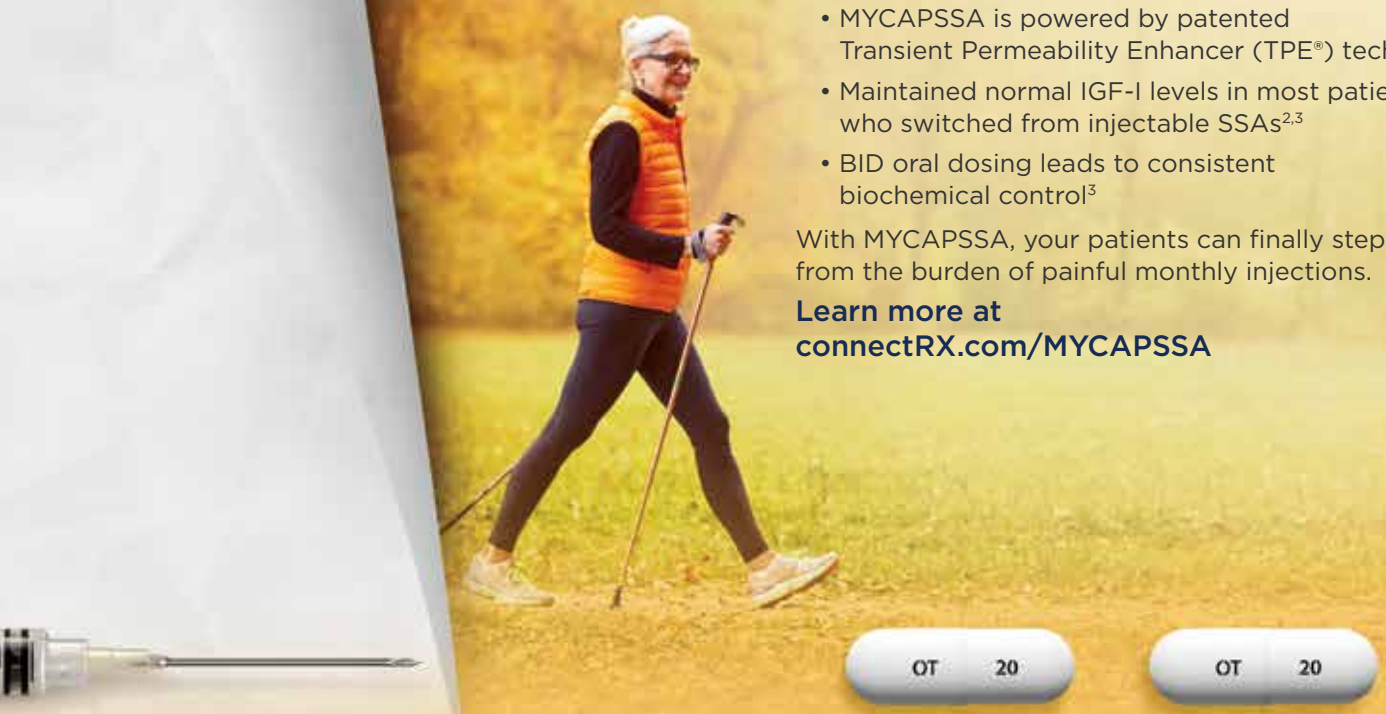
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ADVERSE REACTIONS

The most common adverse reactions (incidence >10%) are nausea, diarrhea, headache, arthralgia, asthenia, hyperhidrosis, peripheral swelling, blood glucose increased, vomiting, abdominal discomfort, dyspepsia, sinusitis, and osteoarthritis.

DRUG INTERACTIONS

The following drugs require monitoring and possible dose adjustment when used with MYCAPSSA: cyclosporine, insulin, antidiabetic drugs, calcium channel blockers, beta blockers, lisinopril, digoxin, bromocriptine, and drugs mainly metabolized by CYP3A4. Counsel women to use an alternative non-hormonal method of contraception or a back-up method when MYCAPSSA is used with combined oral contraceptives.
Patients taking proton pump inhibitors, H2-receptor antagonists, or antacids concomitantly with MYCAPSSA may require increased dosages of MYCAPSSA.

PREGNANCY

Advise premenopausal females of the potential for an unintended pregnancy.

To report SUSPECTED ADVERSE REACTIONS, contact the product information department at 1-844-312-2462 or FDA at 1-800-FDA-1088 or *www.fda.gov/medwatch*

References: 1. Colao A, et al. *Nat Rev Dis Primers* 2019;5(1):20. **2.** MYCAPSSA. Prescribing information. Chiasma, Inc.;2020. **3.** Samson SL, et al. *J Endocr Soc.* 2020;4(suppl 1):OR23-07. https://doi.org/10.1210/jendso/bvaa046.211 **4.** Melmed S, et al. *J Clin Endocrinol Metab.* 2015;100 (4):1699-1708.

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

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MYCAPSSA® is the first and only FDA-approved oral somatostatin analog (SSA) for appropriate patients with acromegaly, providing effective and consistent biochemical control while freeing patients from the burden of injections.[1-3]

- MYCAPSSA maintained normal IGF-I levels in most patients who switched from injectable SSAs[2,3]
- BID oral dosing leads to consistent biochemical control[3]
- MYCAPSSA (octreotide) was generally well tolerated in clinical trials[3,4]

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Brief Summary of Prescribing Information

MYCAPSSA® (octreotide) delayed-release oral capsules, for oral use

This summary does not include all the information needed to use MYCAPSSA safely and effectively. See full Prescribing Information for MYCAPSSA (**https://label.mycapssa.com/prescribinginformation**).

INDICATION AND USAGE

MYCAPSSA (octreotide) delayed-release capsules, for oral use, is a somatostatin analog indicated for long-term maintenance treatment in acromegaly patients who have responded to and tolerated treatment with octreotide or lanreotide.

CONTRAINDICATIONS

MYCAPSSA can cause a serious allergic reaction, including anaphylactic shock, and should not be used in patients who are allergic to octreotide or any of the components of MYCAPSSA.

ADMINISTRATION

MYCAPSSA should be taken on an empty stomach with a glass of water.

WARNINGS AND PRECAUTIONS

MYCAPSSA can cause problems with the gallbladder. Monitor patients periodically. Discontinue if complications of cholelithiasis are suspected.

Blood sugar, thyroid levels, and vitamin B_{12} levels should be monitored and treated accordingly.

Bradycardia, arrhythmia, or conduction abnormalities may occur. Treatment with drugs that have bradycardia effects may need to be adjusted.

ADVERSE REACTIONS

The most common adverse reactions, occurring in more than 10% of people taking MYCAPSSA, are nausea, diarrhea, headache, arthralgia, asthenia, hyperhidrosis, peripheral swelling, increased blood glucose, vomiting, abdominal discomfort, dyspepsia, sinusitis, and osteoarthritis.

DRUG INTERACTIONS

The following drugs require monitoring and possible dose adjustment when used with MYCAPSSA: cyclosporine, insulin, antidiabetic drugs, calcium channel blockers, beta blockers, lisinopril, digoxin, bromocriptine, and drugs mainly metabolized by CYP3A4. Counsel women to use an alternative non-hormonal method of contraception or a back-up method when MYCAPSSA is used with combined oral contraceptives.

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SPECIAL POPULATIONS

Advise premenopausal females of the potential for an unintended pregnancy.

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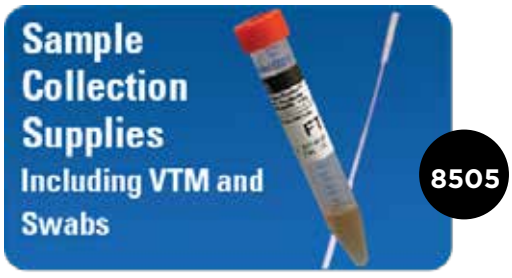
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LIBTAYO®
(cemiplimab-rwlc)
Injection 350 mg

A breakthrough for patients with advanced CSCC[1]

LIBTAYO® is a programmed death receptor-1 (PD-1) blocking antibody indicated for the treatment of patients with metastatic cutaneous squamous cell carcinoma (mCSCC) or locally advanced CSCC (laCSCC) who are not candidates for curative surgery or curative radiation.[1]

For patients with mCSCC or laCSCC receiving 3 mg/kg every 2 weeks in Study 1540:



31% PR
(partial response)†

15% CR
(complete response)‡

ORR: 63 out of 137 patients (95% CI, 37%-55%)[1,2]

79% of responders (50 out of 63 patients) reached a DOR of ≥6 months[1,2]*

54% of responders (34 out of 63 patients) reached a **DOR of ≥12 months**[1,2]*

Median DOR was not reached (range: 1.9–24.2+ months)[1-3]*

*Median duration of follow-up was 11.1 months for combined CSCC in Study 1540.[1] See additional study design details below.

In an additional cohort in Study 1540, 56 mCSCC patients received LIBTAYO at a dose of 350 mg intravenously every 3 weeks for up to 54 weeks. With a median duration of follow-up of 8.0 months, the confirmed ORR was 41% (95% CI: 28, 55), and 65% of responders had a DOR ≥6 months.[1]

Median DOR was not reached (range: 2.1–11.1+ months)[2]

Plus sign (+) denotes ongoing at last assessment.

- **Study 1540**—EMPOWER-CSCC 1—was a global, pivotal, open-label, nonrandomized, multicohort study that included a total of 193 patients with mCSCC or laCSCC 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 cutoff for Study 1540 data in the USPI is September/October 2018[2]
- The major efficacy outcome measures were confirmed ORR, defined as CR plus PR as assessed by independent central review (ICR), and ICR-assessed DOR[1]
- Study 1540 excluded patients with autoimmune disease who required systemic therapy with immunosuppressant agents within 5 years; history of solid organ transplant; prior treatment with anti–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 ECOG PS ≥2[1]

The recommended dosage of LIBTAYO is 350 mg administered as an intravenous infusion over 30 minutes every 3 weeks until disease progression or unacceptable toxicity.[1]

†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 diameters of target lesions, per WHO Criteria. Nontarget lesions could not have progressive disease, and there could be no new lesions. 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. Nontarget lesions also had to be a complete response, and there could be no new lesions. Any pathological lymph nodes (whether target or nontarget) must have reduction in short axis to <10 mm (<1 cm). Only includes patients with complete healing of prior cutaneous involvement; patients with laCSCC in Study 1540 required biopsy to confirm CR.[1,2]

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. Immune-mediated adverse reactions affecting more than one body system can occur simultaneously. 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® (cemiplimab-rwlc) demonstrated meaningful tumor reduction in clinical trial patients[1,2]

Partial responses

These are examples from the 31% of patients who had a partial response 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 composite (RECIST 1.1 + WHO Criteria) evaluation by ICR
- Best percent change in target lesion(s): 91.9% per WHO Criteria

Screening | **After 16 weeks** | **After 32 weeks**



Metastatic CSCC

History

- 66-year-old male
- Periclavicular lesions

Outcomes*

- Best response: PR per composite (RECIST 1.1 + WHO Criteria) evaluation by ICR
- Best percent change in target lesion(s): 71.1% per RECIST 1.1

Screening | **After 24 weeks** | **After 48 weeks**



*Results as of data cutoff October 27, 2017.[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]

DOR=duration of response; ECOG=Eastern Cooperative Oncology Group; ICR=independent central review; PS=performance status; 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 (continued)

Warnings and Precautions (continued)

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, Stevens-Johnson Syndrome (SJS) and toxic epidermal necrolysis (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 35% of patients. Serious adverse reactions that occurred in ≥2% of patients were pneumonitis, cellulitis, sepsis, and pneumonia. The most common Grade 3-4 adverse reactions (≥2%) were cellulitis, anemia, hypertension, pneumonia, musculoskeletal pain, fatigue, pneumonitis, sepsis, skin infection, and hypercalcemia
- LIBTAYO was permanently discontinued due to adverse reactions in 8% of patients; adverse reactions resulting in permanent discontinuation were pneumonitis, cough, pneumonia, encephalitis, aseptic meningitis, hepatitis, arthralgia, muscular weakness, neck pain, soft tissue necrosis, complex regional pain syndrome, lethargy, psoriasis, rash maculopapular, proctitis, and confusional state
- The most common adverse reactions (incidence ≥20%) were fatigue, rash, and diarrhea musculoskeletal pain, and nausea

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 pages.

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 website. https://clinicaltrials.gov/ct2/show/study/NCT02760498. Updated July 16, 2020. Accessed July 25, 2020.

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

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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 (mCSCC) or locally advanced CSCC (laCSCC) 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. Immune-mediated adverse reactions affecting more than one body system can occur simultaneously.

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, Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (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 mCSCC (nodal or distant), 65 patients with laCSCC, 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 219 patients with advanced CSCC (metastatic or locally advanced disease) in Study 1423 and Study 1540 *[see Clinical Studies (14)]*. Of these 219 patients, 131 had mCSCC (nodal or distant) and 88 had laCSCC. Patients received LIBTAYO 1 mg/kg every 2 weeks (n=1), 3 mg/kg every 2 weeks (n=162) or 350 mg every 3 weeks (n=56) as an intravenous infusion until disease progression, unacceptable toxicity, or completion of planned treatment. The median duration of exposure was 38 weeks (2 weeks to 110 weeks).

The safety population characteristics were: median age of 72 years (38 to 96 years), 83% male, 96% white, and European Cooperative Oncology Group (ECOG) performance score (PS) of 0 (44%) and 1 (56%).

The most common adverse reactions reported in at least 20% of patients were fatigue, rash, diarrhea, musculoskeletal pain, and nausea. The most common Grade 3-4 adverse reactions (≥ 2%) were cellulitis, anemia, hypertension, pneumonia, musculoskeletal pain, fatigue, pneumonitis, sepsis, skin infection, and hypercalcemia. LIBTAYO was permanently discontinued due to adverse reactions in 8% of patients; adverse reactions resulting in permanent discontinuation were pneumonitis, cough, pneumonia, encephalitis, aseptic meningitis, hepatitis, arthralgia, muscular weakness, neck pain, soft tissue necrosis, complex regional pain syndrome, lethargy, psoriasis, rash maculopapular, proctitis, and confusional state. Serious adverse reactions occurred in 35% of patients. Serious adverse reactions that occurred in at least 2% of patients were pneumonitis, cellulitis, sepsis, and pneumonia.

Table 1 summarizes the adverse reactions that occurred in ≥ 10% of patients and Table 2 summarizes Grade 3 or 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=219	
	All Grades %	Grades 3-4 %
General and Administration Site		
Fatigue[a]	34	3
Skin and Subcutaneous Tissue		
Rash[b]	31	1
Pruritus[c]	18	0
Gastrointestinal		
Diarrhea[d]	25	0.5
Nausea	21	0
Constipation	13	0.5
Vomiting	10	0.5
Musculoskeletal and Connective Tissue		
Musculoskeletal pain[e]	24	3
Arthralgia	11	1
Respiratory		
Cough[f]	14	0

(continued)

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

Adverse Reactions	LIBTAYO N=219	
	All Grades %	Grades 3-4 %
Hematology		
Anemia	11	4
Endocrine		
Hypothyroidism	10	0
Metabolism and Nutrition		
Decreased appetite	10	0

Toxicity was graded per National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE) v.4.03

a. Fatigue is a composite term that includes fatigue and asthenia
b. Rash is a composite term that includes rash, rash maculopapular, erythema, dermatitis, dermatitis bullous, rash generalized, pemphigoid, rash erythematous, rash macular, rash pruritic, drug eruption, psoriasis, and skin reaction
c. Pruritus is a composite term that includes pruritus and pruritus allergic
d. Diarrhea is a composite term that includes diarrhea and colitis
e. Musculoskeletal pain is a composite term that includes back pain, pain in extremity, myalgia, musculoskeletal pain, and neck pain
f. Cough is a composite term that includes cough and upper airway cough syndrome

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 (%)[a]
Chemistry	
Increased aspartate aminotransferase	2
Increased INR	2
Hematology	
Lymphopenia	9
Anemia	5
Electrolytes	
Hyponatremia	5
Hypophosphatemia	4
Hypercalcemia	2

Toxicity graded per NCI CTCAE v. 4.03

[a.] 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 467 patients who received LIBTAYO. The incidence of cemiplimab-rwlc treatment-emergent ADAs was 1.1% using an electrochemiluminescent (ECL) bridging immunoassay; 0.2% 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 *[see Clinical Pharmacology (12.1)]*. 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 219 mCSCC or laCSCC patients who received LIBTAYO in clinical studies, 34% were 65 years up to 75 years and 41% were 75 years or older. No overall differences in safety or effectiveness were observed between these subjects and younger subjects.

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From Point of Care at Abbott

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DRUGS OF ABUSE TESTING AND ROUTINE CHEMISTRY PANELS ON A SINGLE ANALYZER

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Carolina Liquid Chemistries Corp. announces the successful launch of Medica Corporation's high-speed benchtop analyzer, the EasyRA®. The updated analyzer now operates at a photometric rate of up to 240 tests per hour or up to 480 tests per hour with ISE. The EasyRA urine drug screening and general chemistry reagents are CLIA categorized as moderately complex. This all-in-one system allows clinical laboratories to screen for drugs of abuse in urine while also allowing healthcare providers to assess routine chemistry panels on a single analyzer.

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Designed by primary care doctors, BPCorrect is a complete home blood pressure monitoring platform consisting of a patient app and clinician portal. While many apps help patients track and display their BP, BPCorrect is the only app that guides patients through a scientific approach to accurately measure BP in the safety and privacy of their homes. BPCorrect works with affordable, validated BP monitors from well-known manufacturers. The web-based clinician portal, available in fall 2020, securely receives patients' readings, summarizes these for providers and clinical staff members, and facilitates billing for remote monitoring. Please visit www.bpcorrect.com for more info.

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From BioFire

The BioFire® FilmArray® Torch is a fully integrated, random, and continuous access system designed to meet your laboratory's syndromic infectious disease testing needs. The BioFire Torch offers a radically reduced benchtop footprint, saving precious space in the lab, and its scalability meets high throughput demands. BioFire® FilmArray® Link Software automatically uploads patient results. Fully compatible with all CLIA Moderate BioFire® FilmArray® Panels, the BioFire Torch helps you maximize efficiency and productivity.

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

- Takes less than 10 minutes to perform, software provides verbal cues
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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
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8530



3 ALLERGY TESTING

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- 80-panel test, NO HIGH RISK (shellfish/peanuts/berries)
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- Options for Immunotherapy Treatment

8531



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
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LABORATORY TEST INFORMATION FOR TODAY'S PATIENTS

BY IRWIN Z. ROTHENBERG, MBA, MS, CLS(ASCP), TECHNICAL WRITER /QUALITY ADVISOR, COLA RESOURCES, INC.

The practice of medicine continues to undergo rapid change, led by advances in molecular diagnostics and genetics, enabling the practice of personalized medicine; advances in mobile and point of care testing technology, enabling medical care in remote as well as non-traditional settings; an ever-more intensely information-driven society where ready access to one's personal medical information is now expected, enabling and encouraging patient involvement in their own healthcare; and finally, change is led by the growing realization of financial constraints due to demographic changes leading to the adoption of a value-based approach to healthcare delivery.

While all aspects of healthcare delivery are changing, it is the clinical laboratory profession that is at the center of this dynamic due to the direct implementation of molecular diagnostic and genetic testing; the massive increase in patient data generated; the increased need for consultative physician communication; and the demand by patients for direct access to test ordering and test results. This has led to the increased visibility, importance, and responsibilities of the laboratory within healthcare delivery.

Healthcare providers recognize the need for encouraging patients' engagement in their own health care, for they know that an empowered patient:

- Understands their health condition and its effect on their body
- Feels able to participate in decision-making with their health care professionals
- Feels able to make informed choices about treatment
- Understands the need to make necessary changes to their lifestyle for managing their condition
- Is able to challenge and ask questions of the health care professionals providing their care
- Takes responsibility for their health and actively seeks care only when necessary
- Actively seeks out, evaluates and makes use of information

PATIENT EDUCATION PROMOTES PATIENT EMPOWERMENT

An estimated 7-10 billion laboratory tests are performed each year in the United States, and laboratory test results influence approximately 70% of medical decisions. Yet the importance of lab tests reaches much further. They enable physicians and patients to:

- Identify disease and begin treatment earlier than ever before
- Individualize care to meet the unique needs of the individual patients
- Monitor patient progress and adjust treatments accordingly
- Foster cost-savings and greater productivity in health delivery

When the patient understands the reasons specific tests are ordered, what the results mean, and how they are utilized in the diagnosis, treatment, and monitoring of their conditions, the more likely it is that the patient will do what is needed to attain and maintain a healthier state.

Educating patients about the meaning of their laboratory tests is even more important now, because in the past, individuals had to visit a healthcare facility—a physician's office, hospital, or clinical laboratory—to have blood or other specimens collected for clinical testing, and they had to wait a period of days

to weeks for a call from their doctor with the results.

WHAT HAS CHANGED?

Direct Access Testing (DAT)

Direct access testing (DAT), permits consumers to order laboratory tests directly from a laboratory without necessarily having to work with their healthcare provider. These test results may be used to monitor an existing health condition, identify a previously unknown medical disorder, or provide data regarding personal health characteristics. Direct access testing is a key element of ongoing efforts to increase individuals' engagement in managing their healthcare, and it is critical that directly accessed test results are accurate and well understood. Laboratory professionals play a vital role in this process.

Currently almost 40 states and the District of Columbia permit consumers to order some or all of their laboratory tests directly— without the involvement of a physician. Similarly, the federal government joined this trend by issuing a regulation directing clinical laboratories to provide individuals with access to their test data upon request. With these new policies in place, consumers are increasingly involved in guiding the health decisions that affect their lives.

Testing is no longer confined to the laboratory. Technological innovations have led to testing that can be performed in other settings.

Point of Care Testing (POCT)

Consumers can also identify, order and buy laboratory services directly in a variety of convenient non-traditional settings, such as retail centers, pharmacies, mobile testing facilities, and wellness centers. These point of care testing (POCT) options provide individuals with immediate access to timely services and results. Many of these tests are performed on waived devices, free from most Federal oversight requirements (as waived tests), by personnel with little or no professional experience.

Direct to Consumer Testing (DTC)

Many more options exist for today's consumers. Individuals now can buy over-the-counter test kits that allow them to collect a sample and mail it to a laboratory that performs the test, or, in some cases, conduct the test themselves in their own homes. This is known as Direct to Consumer Testing. A major boost in utilization of DTC testing is the advent of home DNA testing. This provides information on an individual's genetic disposition or risk for certain diseases or conditions. This knowledge may help individuals make decisions about lifestyle choices.

A concern about DTC laboratory testing:

While this can provide valuable information to individuals about their health status in a timely and convenient manner, questions have arisen about whether consumers have enough background knowledge and information to make sound decisions based on their test results. Consumers might not understand the limitations associated with some tests nor do they necessarily have the knowledge to interpret the tests without input from healthcare professionals. Over the past decade policymakers have been struggling to balance these concerns with a growing desire of individuals to take a more active role in making decisions affecting their health. Regardless of the method or setting, by which patients order their own tests, they must have the correct and complete information to understand what the results mean, when it is necessary to follow up with physicians visits, and when to seek immediate help.

PERSONALIZED MEDICINE:

Personalized medicine, defined as the tailoring of medical treatment to the individual characteristics of each patient, is profoundly impacting all aspects of patient care, including prevention, diagnosis, treatment, and follow up. This approach relies on understanding how a person's unique molecular and genetic profile makes them susceptible to certain diseases.

If a person's genomic information indicates a higher-than-average risk of developing diabetes or a particular form of cancer, that person may choose a lifestyle, or sometimes be prescribed medications, to better regulate the aspects of health and wellness over which he or she has control. The person may benefit in the long run from making preventive lifestyle choices that will help counteract the biological risk. To have successful patient management of these potential health issues, there must be buy-in by the patient to the necessary regimens, including appropriate laboratory testing. Educating the patient on how these tests work, what the results mean in terms of potential for developing these diseases, and the ramifications that can follow are vital.

TEST REPORTING AND INTERPRETATION

Laboratory reports have been developed to provide specific information to highly trained and knowledgeable healthcare providers. As such, the reports typically provide a numeric value and a reference interval, and may also include a brief description of the result. This minimal information, when considered with all other factors such as any symptoms of disease that may be present, is sufficient for healthcare professionals to make clinical decisions. An individual consumer likely will need far greater context to fully understand the meaning of the test and to determine next steps. For example, an abnormal test result outside the reference interval may or may not indicate an underlying health problem. Alternatively, an individual may be falsely reassured by a test result in the normal range even when signs and symptoms warrant medical attention. Finally, consumers may not understand the limitations of the tests and therefore may interpret the results of their tests incorrectly.

Laboratory professionals can play a vital role in all aspects of this consumer-driven process, including educating individuals about the benefits and limitations associated with tests and assisting in the selection of the most appropriate test for that particular person. In addition, highly trained and

experienced laboratorians can assist in the interpretation of test results and can provide consumers guidance on whether additional testing is required to confirm or clarify results, directing them to medical professionals for any necessary follow-up care. Patients can also access reliable information electronically.

RESOURCES FOR EDUCATING PATIENTS ABOUT THEIR TEST RESULTS

In summation, patient education about lab testing can be provided in many ways, including through:

- The physician directly
- Laboratory staff and other ancillary healthcare providers who have the education to provide this information, such as nurses, and pharmacists
- Reference laboratories, where patients can visit directly or receive information via mail or online
- Government information sites such as the FDA, and the CDC
- Private laboratory information sites, such as Lab Tests Online; or Health Network Laboratories
- Laboratory testing information provided online by major medical clinics and hospitals
- Health insurance companies
- Laboratory profession sites such as the American Association for Clinical Chemistry (AACC); the American Society for Microbiology(ASM), and the American Society for Clinical Pathology(ASCP)
- Laboratory Accreditation organizations, such as the American College of Physicians (CAP), COLA and The Joint Commission

PATIENT'S PREFERENCES FOR RECEIVING LABORATORY TEST RESULTS

An important consideration when setting up a system for educating patients about their lab test results is an awareness of preferences for receipt of these results. In a study conducted in 2015 to identify these preferences, all 200 patients in this study preferred online delivery. Also, 82.5% (n = 165) preferred to receive both normal and abnormal test results this way. The main reason for receiving results online was time savings, which was reported by 77% of participants, followed by lowering the chance of missing the results (31%). About 40% of participants thought e-mail notification was more secure than accessing the results through a facility website. Findings showed that although patients wanted to benefit from online services for receiving their test results, they were concerned about confidentiality and security. Before using online technologies, security measures necessary to protect patient privacy and to gain the trust of patients should be assured.

CONCLUSION

Patient education about their laboratory test results is the most effective response for patient empowerment by the healthcare profession, whether for testing performed in the traditional setting of a physician office laboratory, a hospital, or a clinic; or in a non-traditional setting such as a pharmacy, a shopping mall, or at home. Patient education is vital for achieving the best value-based healthcare, and to promote long-term partnerships between physicians and their patients.

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ASSESSING AND MONITORING COVID-19 PATIENTS.

Urgent care facilities, primary care practices, and other outpatient settings at the front lines of the COVID-19 pandemic need on-site testing solutions to support patient assessment and monitoring. With-patient testing can lead to better healthcare performance by facilitating decisions that can optimize patient outcomes in real time, improving the quality of patient care.

For facilities treating COVID-19 patients, having rapid, accurate diagnostic test results may be useful when assessing or monitoring patients for:

- **C-Reactive Protein (CRP)**
  Levels may be elevated in COVID-19 cases, especially severe cases.[2-15]
- **Liver, Kidney and Cardiac function**
  Elevated levels of the following biomarkers may be indicators of COVID-19 severity:[16-27]
  - Alanine Aminotransferase (ALT)[16,17,20-27]
  - Albumin (ALB)[16,19-22,25-27]
  - Aspartate Aminotransferase (AST)[16,17,19-21,23-26]
  - Creatine Kinase (CK)[16,18,20,22-24]
  - Creatinine (CREAT)[16,22,23,25,27]
  - Total Bilirubin (TBILI)[16,20,25,27]



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The Piccolo Xpress does not directly diagnose COVID-19.

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ALB, ALP, ALT, AMY, AST, BUN, Ca, Crea, Glu, GGT, TP, UA, CRP, eGFR*



MetLyte Plus CRP
Na+, K+, Cl-, tCO_2, BUN, Crea, Glu, CK, CRP, eGFR*



Hepatic Function Panel
ALB, ALP, ALT, AST, tBIL, dBIL, TP

To learn how the Piccolo Xpress portable diagnostic analyzer can help transform your patient care, contact your Abbott Point of Care Representative or visit www.pointofcare.abbott

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The long-acting anti-CGRP injection with the option of dosing only 4 times a year[1]*

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*"Long-acting" was defined as efficacy measured over a 12-week period following a 225 mg x 3 (675 mg) SQ dose.[1]

CGRP: calcitonin gene-related peptide; **SQ:** subcutaneous.

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 the Brief Summary of the Prescribing Information on the adjacent page.

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

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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 and gestational hypertension 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-004.

teva

FRE-42210 February 2020

FEATURE

LOOKING AHEAD WHAT THE FUTURE WILL BRING

DAVID KLIFF, THE DIABETIC INVESTOR

When it comes to innovate new therapies or medical devices there is a lag time between introduction, adoption and full-blown usage. This pattern is playing out right this very moment with continuous glucose monitoring. It should surprise no one that early adopters of this revolutionary technology are endocrinologists and their intensively managed patients. CGM is successfully penetrating this segment of the diabetes patient population.

Yet as we look to the future CGM offers the potential to forever change how all patients with diabetes manage their condition. Intensively managed patients may be the early adopters of this technology, but they are just the tip of the iceberg. So let's take out the crystal ball and look to see how CGM will be used in the future.

In the near-term future thanks to CGM technology we will soon see what was once thought to be a dream, a true closed loop insulin delivery system or what some call an artificial pancreas. The systems available today driven by insulin pumps combined with CGM and insulin dosing algorithms will look like rotary telephone technology in just a few short years. It won't be long before these systems morph into a system that a patient slaps on, turns on and forgets about.

As whiz bang and way cool as these systems will be, they will not for a variety reasons impact a substantial percentage of the insulin using patient population. While insulin pump therapy has been around for more than 30 years, is well established and readily accessible only 35% of the Type 1 population and less than 5% of the Type 2 population use an insulin pump, numbers that have not change much over the last 10 years even with all the advancements in insulin pump therapy.

Therefore we will see systems that combine a connected insulin pen, CGM, insulin dosing algorithm and app. While these systems will require a higher level of patient participation, we anticipate wide spread adoption. Insulin dosing has always been a tricky subject for physicians and their patients as there are multiple variables that go into the calculation. Thanks to CGM and insulin dosing algorithms much of the heavy lifting once performed by the patient will be done by the system.

One of the misunderstood aspects of these systems is they are not static but dynamic. Or put another way the system learns and adjusts. Perhaps the best way to think about this is insulin dosing algorithms are effectually a form of artificial intelligence. Like other forms of AI the more data they gather the more they are used they more they learn. We anticipate that the early studies now underway for these systems will show excellent results which will pave the way for wide spread adoption.

Adding fuel to the fire here will be another advantage as these systems will be cost effective, will require little in the way of patient training while providing excellent outcomes. The only obstacle these systems cannot overcome is the human element, to be effective the patient has to follow the instructions given by the system. The system can gather the data and learn but the patient must do their part to fully benefit.

However we see the real potential with patients who do not use insulin, by far the largest group of patients. As we all know the biggest obstacle standing between this patient population and better outcomes is therapy compliance or adherence. Put simply we'd see much better outcomes if patients took their meds as they are prescribed. That they did not skip doses or manipulate doses.

Thanks to CGM physicians will have a clearer picture as to what is and what is not going on. The key of course is a CGM that is patient friendly. Thankfully that day is almost here as soon we will have CGM systems that are slap it on turn it on



and that's it. No fingerstick calibrations, no extra devices to collect the data and best of all they will be very affordable.

Even better for the physicians the analytics will be done for them, they will know before seeing the patient what is and what is not happening. We hate to state the obvious but there are only so many reasons why a patient is not achieving good control. Nine times out of ten it usually comes down to what we said before therapy adherence. Armed with CGM data and the analytics the physician can show the patient what's going on, no more guess work.

We anticipate the healthcare system and economics to drive adoption of these systems. Diabetes is not just growing at epidemic rates it is becoming a huge financial crisis for payors and employers. Numerous studies have shown that patients under good control not only live healthier lives but also avoid many of the very costly complications due to poorly controlled diabetes.

Even with all the advancements we have seen in diabetes therapies and devices one indisputable facts remains, a fact that has not changed in the last 20 years, almost two-thirds of all patients are not under good control. Hence the reason diabetes has morphed from a healthcare crisis into an economic crisis. Thanks to CGM, insulin dosing algorithms and advanced analytics i.e. AI we now have the tools to do what has never been done before, forever change how diabetes is managed.

Yet diabetes is not the only condition where CGM can have this impact. In the future CGM will become an equally powerful tool to combat another, excuse the expression, huge problem. Research indicates that CGM can also be used to combat obesity. The same sophisticated algorithms and analytics which will help patients better manage their diabetes will be adjusted to help a patient lose weight. Although in the very early stages this transformation is underway with early studies looking very promising.

Some early research also suggest CGM can be used to monitor cardiovascular conditions. Again this work is very early stage but now that smartwatches can monitor heart rates this early research indicates that when this data is combined with CGM data preventive measures can be taken.

Today everyone looks at CGM as strictly a tool for patients with diabetes. More specifically they see it as tool for insulin using patients. But as we noted earlier this is just the tip of the iceberg and not just for diabetes. These systems we have today have already achieved the necessary level of accuracy. Costs are coming down which will drive even greater adoption. The last domino to fall will be the results from the studies which are now underway. Studies that go beyond uses in diabetes but obesity and cardiovascular too.

There is no question that CGM has a very bright and very promising future. We know of few other tools which have the transformative potential of CGM. It won't happen overnight and there surly will be some hiccups along the way. But one thing is clear CGM is here and here to stay.



IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Few cases (0.36%) of adverse reactions of cystitis, pyelonephritis and other upper urinary tract infection (UTI) have been reported in Phexxi™ clinical studies. Of these, one case of pyelonephritis was considered serious and required hospitalization. Avoid use of Phexxi™ in females of reproductive potential with history of recurrent urinary tract infection or urinary tract abnormalities.

ADVERSE REACTIONS

Most common adverse reactions were vulvovaginal burning sensation, vulvovaginal pruritus, vulvovaginal mycotic infection, urinary tract infection, vulvovaginal discomfort, bacterial vaginosis, vaginal discharge, genital discomfort, dysuria, and vulvovaginal pain.

Patients should be counseled on the following:

- **To contact and consult with their healthcare provider for severe or prolonged genital irritation or experiencing urinary tract symptoms.**
- **To discontinue Phexxi™ if they develop a local hypersensitivity reaction.**
- **That Phexxi™ does not protect against HIV infection or other sexually transmitted infections.**

To report SUSPECTED ADVERSE REACTIONS, contact Evofem at toll-free phone 1-833-EVFMBIO or you may contact FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.



INDICATIONS AND USAGE
Phexxi™ is indicated for the prevention of pregnancy in females of reproductive potential for use as an on-demand method of contraception.

LIMITATIONS OF USE
Phexxi™ is not effective for the prevention of pregnancy when administered after intercourse.

Please see full Prescribing Information for Phexxi™.
Please see Brief Summary on the following page.

REFERENCES: 1. Phexxi™ [Prescribing Information]. Evofem Biosciences, Inc: San Diego, CA; May 2020. **2.** Phexxi™ Vaginal Gel. Medi-Span®; June 8, 2020. **3.** Bayer LL, Jensen JT. ACIDFORM: a review of evidence. *Contraception*. 2014;90:11-18. **4.** Nayak S, Avery A, McLeod Griffiss J, Charles CD, Culwell KR. A randomized placebo-controlled pilot study of the effect and duration of Amphora, a multipurpose vaginal pH regulator, on vaginal pH. *Clin Exp Obstet Gynecol*. 2019;46(5):736-742.

EVOFEM BIOSCIENCES

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phexxi™

(lactic acid, citric acid, and potassium bitartrate) Vaginal Gel 1.8%, 1%, 0.4%

BRIEF SUMMARY: Consult the Package Insert for complete Prescribing Information

INDICATIONS AND USAGE

PHEXXI™ is indicated for the prevention of pregnancy in females of reproductive potential for use as an on-demand method of contraception.

LIMITATIONS OF USE

PHEXXI is not effective for the prevention of pregnancy when administered after intercourse.

WARNINGS AND PRECAUTIONS

Cystitis and Pyelonephritis

Among 2804 subjects who received PHEXXI in Studies 1 and 2, 0.36% (n=10) reported adverse reactions of cystitis, pyelonephritis, or other upper urinary tract infection (UTI). Of these, one case of pyelonephritis was considered serious and required hospitalization. Avoid use of PHEXXI in females of reproductive potential with a history of recurrent urinary tract infection or urinary tract abnormalities.

ADVERSE REACTIONS

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 safety of PHEXXI (pre-filled applicator with 5-gram dose) has been evaluated in two clinical trials (Study 1 and Study 2) in 2804 subjects (over 19,000 cycles of exposure). The racial/ethnic distribution was 66% White, 27% Black or African American, 2% Asian, 1% American Indian or Alaska Native, 0.3% Native Hawaiian or Pacific Islander, and 5% other; 32% of the study population was Hispanic. Study 1 included a one-year extension phase where 342 U.S. subjects were exposed to PHEXXI for 13 cycles.

Hypersensitivity Reaction:

Of the 2804 PHEXXI-treated subjects in Studies 1 and 2, one subject reported a suspected drug hypersensitivity. Avoid PHEXXI use in females of reproductive potential with suspected hypersensitivity to the ingredients in PHEXXI.

The most common adverse reactions (≥10%) in the U.S. population in Studies 1 and 2 (n = 2480) were: vulvovaginal burning sensation (18.0%) and vulvovaginal pruritus (14.5%). The majority of these adverse reactions were mild and few led to discontinuation. Table 1 summarizes the most common adverse reactions (≥ 2%) reported by subjects using PHEXXI in the U.S.

Table 1. Adverse Reactions that Occurred in ≥ 2% of Subjects Who Used PHEXXI to Prevent Pregnancy (Studies 1 and 2 – U.S. population only)

Adverse Reaction	PHEXXI (N=2480) (%)
Vulvovaginal Burning Sensation	18.0
Vulvovaginal Pruritus	14.5
Vulvovaginal Mycotic Infection*	9.1
Urinary Tract Infection†,‡	9.0
Vulvovaginal Discomfort	9.0
Bacterial Vaginosis	8.4
Vaginal Discharge	5.5
Genital Discomfort	4.1
Dysuria	3.1
Vulvovaginal pain	2.1

*Includes preferred terms (PT) vulvovaginal mycotic infection and vulvovaginal candidiasis.
†Includes PTs urinary tract infection, streptococcal urinary tract infection, Escherichia urinary tract infection, and urinary tract infection bacterial.
‡Does not include PTs cystitis, kidney infection, and pyelonephritis [see *Warnings and Precautions (5.1) of PHEXXI Full Prescribing Information*].

Among subjects who used PHEXXI in Studies 1 and 2, 1.6% discontinued from the clinical trials due to an adverse reaction. The most common adverse reactions leading to study discontinuation were vulvovaginal burning sensation (0.7%); and vulvovaginal pruritus and vulvovaginal discomfort (0.1% each).

Adverse Reactions in Male Partners:

Among male partners of subjects who used PHEXXI for contraception in Study 2, 9.8% (131 of 1330) reported symptoms of local discomfort (burning, itching, pain, and "other"). Of these local discomfort symptoms, 74.7% were mild, 21.4% were moderate, and 3.9% were severe. Two subjects discontinued participation in the study due to male partner symptoms.

USE IN SPECIFIC POPULATIONS

Pregnancy

Risk Summary

There is no use for PHEXXI in pregnancy; therefore, discontinue PHEXXI during pregnancy. There are no data with the use of PHEXXI in pregnant women or animals. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2 to 4 percent and 15 to 20 percent, respectively.

Lactation

Risk Summary

There are no data on the presence of lactic acid, citric acid, and potassium bitartrate or their metabolites in human milk, the effects on the breastfed infant, or the effects on milk production.

Pediatric Use

The safety and effectiveness of PHEXXI have been established in females of reproductive potential.

Efficacy is expected to be the same for post-menarchal females under the age of 17 as for users 17 years and older. The use of PHEXXI before menarche is not indicated.

PATIENT COUNSELING INFORMATION

See FDA-approved patient labeling.

Advise the patient to read the Patient Information and FDA-approved patient labeling (Instructions for Use).

Advise the patient:

- To intravaginally administer the contents of one pre-filled single-dose applicator of PHEXXI before **each** episode of vaginal intercourse and to administer an additional dose if intercourse does not occur within one hour of administration [*see Dosage and Administration (2.1) of PHEXXI Full Prescribing Information*].
- To consult their healthcare provider for severe or prolonged genital irritation [*see Adverse Reactions (6.1) of PHEXXI Full Prescribing Information*].
- To discontinue PHEXXI if they develop a local hypersensitivity reaction [*see Adverse Reactions (6.1) of PHEXXI Full Prescribing Information*].
- To contact their health care provider if experiencing urinary tract symptoms [*see Warnings and Precautions (5.1) of PHEXXI Full Prescribing Information*].
- That PHEXXI does not protect against HIV infection and other sexually transmitted infections.

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U.S. Patent 6,706,276

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To report SUSPECTED ADVERSE REACTIONS, contact Evofem at toll-free phone 1-833-EVFMBIO or you may contact FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

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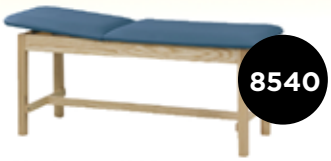
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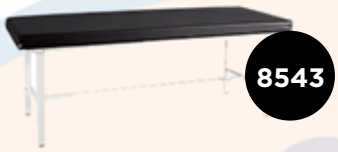
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