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European Commission Approves Pfizer's VELSIPITY® for Patients with Moderately to Severely Active Ulcerative Colitis

Monday, February 19, 2024 - 07:45am

- *VELSIPITY is the first and only oral advanced ulcerative colitis therapy approved for use in patients 16 years of age or older in the EU*

NEW YORK--(BUSINESS WIRE)-- Pfizer Inc. (NYSE: PFE) announced today that the European Commission (EC) has granted marketing authorization for VELSIPITY® (etrasimod) in the European Union to treat patients 16 years of age and older with moderately to severely active ulcerative colitis (UC) who have had an inadequate response, lost response, or were intolerant to either conventional therapy, or a biological agent.

"For the 2.6 million people in Europe living with UC, the unpredictable physical, mental, and emotional impacts of the condition can be debilitating. They may cycle through several different conventional treatment options to find relief for their symptoms," said Séverine Vermeire, MD, PhD, Professor of Medicine at KU Leuven and an investigator in the ELEVATE Registrational Program. "The approval of VELSIPITY helps bridge the gap for those with moderately to severely active UC who need an effective advanced treatment but may be apprehensive about using injectable therapies like biologics."

The marketing authorization for VELSIPITY is valid in all 27 EU member states as well as Iceland, Liechtenstein, and Norway. This authorization follows the recommendation for approval by the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) in December 2023. It also follows VELSIPITY's approval for adults with moderately to severely active UC by the U.S. Food and Drug Administration (FDA) in October 2023, and for adults with moderately to severely active UC who have had an inadequate response, lost response, or were intolerant to either conventional therapy or an advanced treatment in Canada in January 2024. Regulatory applications for VELSIPITY in UC have been submitted to additional countries around the world for review.

"VELSIPITY can help appropriate patients with UC who are struggling to achieve remission on conventional therapies," said Alexandre de Germay, Chief International Commercial Officer, Executive Vice President, Pfizer. "With convenient, once-daily oral dosing and a favorable benefit-risk profile, VELSIPITY is an attractive potential treatment option and Pfizer is proud to bring this medicine to appropriate UC patients as young as 16 years old in the European Union."

The approval was based on results from the ELEVATE UC Phase 3 registrational program (ELEVATE UC 52 and ELEVATE UC 12) that evaluated the safety and efficacy of VELSIPITY 2 mg once-daily on clinical remission in UC patients who had previously failed or were intolerant to at least one conventional, biologic, or Janus kinase (JAK) inhibitor therapy. Additionally, ELEVATE UC 52 and ELEVATE UC 12 were the only

studies of advanced therapies for UC to include patients with isolated proctitis, which affects approximately 30% of those diagnosed with UC. Both studies achieved all primary and key secondary efficacy endpoints, with a favorable safety profile consistent with previous studies of VELSIPITY. VELSIPITY also demonstrated improvement in the total inflammatory bowel disease questionnaire score, which measures health-related quality of life. The most common adverse reactions were lymphopenia (11%) and headache (7%).

About Ulcerative Colitis

UC is a chronic, immune-mediated inflammatory bowel disease characterized by diffuse mucosal inflammation.[1] Clinical symptoms of UC may include but are not limited to frequent diarrhea, bowel urgency, rectal bleeding, abdominal pain, fatigue, fever and anemia.[2,3,4] Its impact can span beyond the physical to other aspects of life due to the chronic and unpredictable nature of symptoms.[5,6]

About VELSIPITY® (etrasimod)

VELSIPITY is a once-daily, oral, sphingosine 1-phosphate (S1P) receptor modulator that selectively binds with S1P receptor subtypes 1, 4, and 5. Regulatory applications for VELSIPITY in ulcerative colitis have been submitted to additional countries including Australia, India, Mexico, Russia, Singapore, Switzerland, Turkey, and the UK.

U.S. INDICATION

VELSIPITY is a selective sphingosine-1-phosphate (S1P) receptor modulator indicated for the treatment of moderately to severely active UC in adults.

U.S. IMPORTANT SAFETY INFORMATION & INDICATION

Do not take VELSIPITY if you:

- have had a heart attack, chest pain (unstable angina), stroke or mini stroke (transient ischemic attack or TIA), and certain types of heart failure requiring hospitalization in the last 6 months
- have or have had a history of unusual heartbeats (arrhythmia) that is not corrected by a pacemaker

Talk to your healthcare provider before taking VELSIPITY if you have any of these conditions or do not know if you have any of these conditions.

VELSIPITY can cause serious side effects, including:

- **Infections:** VELSIPITY can increase your risk of serious infections. These infections can be life-threatening and cause death. VELSIPITY lowers the number of white blood cells (lymphocytes) in your blood. This usually returns to normal within 4 to 5 weeks after you stop taking VELSIPITY. Your healthcare provider will test your blood before you start taking VELSIPITY. Your healthcare provider may delay or stop your VELSIPITY treatment if you have an infection. Call your healthcare provider right away if you have any of these symptoms of an infection during treatment with VELSIPITY, and for 5 weeks after you stop taking VELSIPITY: fever or high temperature, pain when peeing or peeing more often than usual as these can be signs of a urinary tract infection, tiredness, flu-like symptoms, or headache with fever, neck stiffness, sensitivity to light, nausea, or confusion as these may be symptoms of meningitis, an infection of the lining around your brain and spine.
- **Slow heart rate (also known as bradyarrhythmia) when you start taking VELSIPITY:** VELSIPITY may cause your heart rate to temporarily slow down especially after you take your first dose. You will

have a test called an electrocardiogram (ECG) to check the electrical activity of your heart before you take your first dose of VELSIPITY. Call your healthcare provider if you experience these symptoms of slow heart rate: feeling dizzy, feeling lightheaded, feeling like your heart is beating slowly or skipping beats, feeling short of breath, feeling confused, feeling tired, or chest pain.

Before taking VELSIPITY, tell your healthcare provider about all of your medical conditions, including if you:

- have a serious infection or an infection that does not go away or that keeps coming back (chronic).
- are unable to fight infections due to a disease.
- have received a vaccine in the past 4 weeks or are scheduled to receive a vaccine. You should be brought up to date with all age-required vaccines before starting treatment with VELSIPITY. VELSIPITY may affect how well a vaccine works. Tell your healthcare provider that you are receiving treatment with VELSIPITY before receiving a vaccine.
- have chickenpox or received the vaccine for chickenpox. Your healthcare provider may do a blood test for the chickenpox virus. You may need to get the full course of the chickenpox vaccine and then wait 4 weeks before you start taking VELSIPITY.
- have a slow heart rate.
- have an irregular or abnormal heartbeat (arrhythmia).
- have heart disease, Class I or II heart failure, history of a heart attack, high blood pressure or uncontrolled high blood pressure.
- have cerebrovascular disease or history of a stroke or ministroke.
- history of repeated fainting.
- have or have had liver problems.
- have or have had skin cancer.
- have breathing problems, including untreated sleep apnea.
- are pregnant or plan to become pregnant. VELSIPITY may harm your unborn baby. Talk with your healthcare provider if you are pregnant or plan to become pregnant. If you are a female who can become pregnant, talk with your healthcare provider and use effective birth control during your treatment with VELSIPITY and for 7 days after you stop taking VELSIPITY. If you become pregnant while taking VELSIPITY or within 7 days after you stop taking VELSIPITY, talk with your healthcare provider and enroll in the VELSIPITY Pregnancy Registry by calling 1-800-616-3791.
- are breastfeeding or plan to breastfeed. It is not known if VELSIPITY passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby if you take VELSIPITY.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Using VELSIPITY with other medicines can cause serious side effects. Especially tell your healthcare provider if you take or have taken:

- medicines to control your heart rhythm (antiarrhythmics), heartbeat, or blood pressure. These may be called beta blockers or calcium channel blockers.
- medicines that affect your immune system.
- certain medicines known as moderate to strong inhibitors of both CYP2C9 and CYP3A4, medicines such as fluconazole. If you are taking fluconazole, you should not take VELSIPITY.
- Rifampin. If you are taking rifampin, you should not take VELSIPITY.

You should not receive **live** vaccines at least 4 weeks before starting VELSIPITY, during treatment with VELSIPITY and for 5 weeks after you stop taking VELSIPITY. Talk to your healthcare provider before you receive a vaccine during treatment and for 5 weeks after treatment with VELSIPITY. If you receive a live

vaccine, you may get the infection the vaccine was meant to prevent. Vaccines may not work as well when given during treatment with VELSIPITY.

VELSIPITY can cause serious side effects, including:

- **Liver problems.** VELSIPITY may cause liver problems. Your healthcare provider will do blood tests to check your liver before you start taking VELSIPITY. Call your healthcare provider right away if you have any of the following symptoms: unexplained nausea, vomiting, stomach area (abdominal pain), tiredness, loss of appetite, yellowing of the whites of your eyes or skin, or dark-colored urine.
- **Increased blood pressure.** Your healthcare provider should check your blood pressure during treatment with VELSIPITY and treat you as needed.
- **A problem with your vision called macular edema.** Your healthcare provider should test your vision around the time you start taking VELSIPITY or at any time you notice vision changes during your treatment with VELSIPITY. Call your healthcare provider right away if you have any of the following symptoms: blurriness or shadows in the center of your vision, sensitivity to light, a blind spot in the center of your vision, or unusually colored vision.
- **Types of skin cancer.** Certain types of skin cancer have happened with medicines in the same class as VELSIPITY. Limit the amount of time you spend in sunlight and ultraviolet (UV) light while taking VELSIPITY. Wear protective clothing and use a sunscreen with a high sun protection factor. Tell your healthcare provider if you have any changes in the appearance of your skin.
- **Swelling and narrowing of the blood vessels in your brain.** A condition called Posterior Reversible Encephalopathy Syndrome (PRES) has happened with drugs in the same class. Symptoms of PRES usually get better when you discontinue treatment. If not treated, PRES may cause a stroke. Call your healthcare provider right away if you have any of the following symptoms: sudden severe headache, sudden confusion, sudden loss of vision or other changes in your vision, or seizure. If you develop any of these symptoms, your healthcare provider will stop treatment with VELSIPITY.
- **Breathing problems.** Some people who take medicines in the same class as VELSIPITY may experience shortness of breath. Your healthcare provider may do tests to check your breathing during treatment with VELSIPITY. Call your healthcare provider right away if you have new or worsening breathing problems.

The most common side effects of VELSIPITY include headache, elevated liver tests, and dizziness. These are not all of the possible side effects of VELSIPITY. For more information, ask your healthcare provider or pharmacist. You may report side effects to FDA at 1-800-FDA-1088. You may also report side effects to Pfizer at 1-800-438-1985.

INDICATION

VELSIPITY is a prescription medicine used to treat adults with moderately to severely active ulcerative colitis. It is not known if VELSIPITY is safe and effective in children.

About Pfizer: Breakthroughs that Change Patients' Lives

At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety, and value in the discovery, development, and manufacture of health care products, including innovative medicines and vaccines. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments, and cures that challenge the most feared diseases of our time. Consistent with our responsibility as one of the world's premier innovative biopharmaceutical companies, we collaborate with health care providers, governments, and local communities to support and expand access to reliable, affordable health care around the world. For more than 175 years, we have worked to make a difference for all who rely on us. We routinely post information that

may be important to investors on our website at www.pfizer.com. In addition, to learn more, please visit us on www.pfizer.com and follow us on X at @Pfizer and @Pfizer_News, LinkedIn, YouTube and like us on Facebook at Facebook.com/Pfizer.

Disclosure Notice

The information contained in this release is as of February 19, 2024. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.

This release contains forward-looking information about VELSIPITY (etrasimod), including its potential benefits, the grant of a marketing authorization by the EC in the EU for VELSIPITY for the treatment of patients 16 years of age and older with moderately to severely active ulcerative colitis who have had an inadequate response, lost response, or were intolerant to either conventional therapy, or a biological agent, and applications pending for VELSIPITY (etrasimod) in other jurisdictions, that involves substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, uncertainties regarding the commercial success of VELSIPITY (etrasimod); the uncertainties inherent in research and development, including the ability to meet anticipated clinical endpoints, commencement and/or completion dates for our clinical trials, regulatory submission dates, regulatory approval dates and/or launch dates, as well as the possibility of unfavorable new clinical data and further analyses of existing clinical data; the risk that clinical trial data are subject to differing interpretations and assessments by regulatory authorities; whether regulatory authorities will be satisfied with the design of and results from our clinical studies; whether and when drug applications may be filed in particular jurisdictions for VELSIPITY (etrasimod) for any potential indications; whether and when any applications that may be pending or filed for VELSIPITY (etrasimod) may be approved by regulatory authorities, which will depend on myriad factors, including making a determination as to whether the product's benefits outweigh its known risks and determination of the product's efficacy and, if approved, whether VELSIPITY (etrasimod) will be commercially successful; decisions by regulatory authorities impacting labeling, manufacturing processes, safety and/or other matters that could affect the availability or commercial potential of VELSIPITY (etrasimod); uncertainties regarding the impact of COVID-19 on Pfizer's business, operations and financial results; and competitive developments.

A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2022 and in its subsequent reports on Form 10-Q, including in the sections thereof captioned "Risk Factors" and "Forward-Looking Information and Factors That May Affect Future Results", as well as in its subsequent reports on Form 8-K, all of which are filed with the U.S. Securities and Exchange Commission and available at www.sec.gov and www.pfizer.com .

References:

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Source: Pfizer Inc.