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European Commission Approves Pfizer’s EMBLAVEO® for Patients with Multidrug-Resistant Infections and Limited Treatment Options

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- *EMBLAVEO® is the first ?-lactam/?-lactamase inhibitor antibiotic combination approved in the European Union for treating serious infections in adult patients caused by multidrug-resistant Gram-negative bacteria, including metallo-?-lactamase-producing bacteria*
- *EMBLAVEO® was reviewed under European Medicines Agency accelerated assessment procedure, used when a pharmaceutical product is of major interest for public health and therapeutic innovation*

NEW YORK--(BUSINESS WIRE)-- Pfizer Inc. (NYSE: PFE) today announced that the European Commission (EC) has granted marketing authorization for EMBLAVEO® (aztreonam-avibactam) for the treatment of adult patients with complicated intra-abdominal infections (cIAI), hospital-acquired pneumonia (HAP), including ventilator-associated pneumonia (VAP), and complicated urinary tract infections (cUTI), including pyelonephritis. It is also indicated for the treatment of infections due to aerobic Gram-negative organisms in adult patients with limited treatment options.

“For healthcare teams treating patients with serious Gram-negative bacterial infections, the prospect of running out of effective treatment options is a daunting but very real threat,” said Yehuda Carmeli, Head, National Institute for Antibiotic Resistance and Infection Control, Tel Aviv Medical Center, Israel, and an investigator in the REVISIT study. “The approval of EMBLAVEO is welcome news for the infectious disease community and provides new hope to critically ill patients affected by antimicrobial resistance.”

Antimicrobial resistance (AMR) – when bacteria, viruses, fungi, and parasites change and find ways to resist the effects of antimicrobial drugs – is recognized as one of the biggest threats to global health.[1] If AMR continues to rise unchecked, minor infections could become life-threatening, and many routine medical procedures such as caesarean sections and hip replacements could become too risky to perform.[1] Multidrug-resistant Gram-negative bacteria are of particular concern due to the high rates of morbidity and mortality they cause.[2,3] Metallo-?-lactamases (MBLs) are a type of enzyme produced by certain bacteria that can result in resistance to antibiotics, and MBL-producing Gram-negative bacteria are on the rise globally.[4] Developing new treatments for infections caused by Gram-negative bacteria has been prioritized by the World Health Organization (WHO) as a critical area of focus due to their increasing spread.[1,5]

“The European Medicines Agency’s accelerated review of EMBLAVEO reflects the urgent need for new treatments to address the threat of antimicrobial resistance,” said Alexandre de Germay, Chief International Commercial Officer, Executive Vice President, Pfizer. “With this approval, Pfizer is proud to take another step forward in its commitment to developing and bringing breakthrough health solutions to patients impacted by serious infectious diseases around the world.”

This approval is based on results from the previously reported Phase 3 program comprising the REVISIT (NCT03329092) and ASSEMBLE (NCT03580044) studies evaluating the efficacy, safety, and tolerability of EMBLAVEO in treating serious bacterial infections due to Gram-negative bacteria, including MBL-producing multidrug-resistant pathogens for which there are limited or no treatment options.[6,7] Data support that EMBLAVEO is effective and well-tolerated, with no new safety findings and a similar safety profile to aztreonam alone.[8]

The marketing authorization of EMBLAVEO is valid in all 27 European Union (EU) member states, as well as in Iceland, Liechtenstein, and Norway. Marketing authorization applications for EMBLAVEO are planned for submission in other countries.

About EMBLAVEO® (aztreonam-avibactam)

EMBLAVEO® is indicated for the treatment of adult patients with complicated intra-abdominal infections (cIAI), hospital-acquired pneumonia (HAP), including ventilator-associated pneumonia (VAP), complicated urinary tract infections (cUTI), including pyelonephritis, and infections due to aerobic Gram-negative organisms with limited treatment options. It combines aztreonam, a monobactam ?-lactam, with avibactam, a recent broad-spectrum ?-lactamase inhibitor.[9,10] MBLs are a class of ?-lactamase enzymes that are not inhibited by current ?-lactamase inhibitors and hydrolyze nearly all ?-lactam antibiotics, with an exception being monobactams such as aztreonam. However, monobactams are degraded by other ?-lactamases that are frequently co-produced with MBLs, limiting the clinical usefulness of aztreonam monotherapy.[9]

The combination of aztreonam with avibactam restores aztreonam's activity against bacteria that co-produce MBLs and other ?-lactamases and provides a well-tolerated and effective treatment option against multidrug-resistant Gram-negative bacteria.[9] These multidrug-resistant Gram-negative bacteria include MBL-producing Enterobacterales, which have been highlighted as a critical priority pathogen by the WHO, and *S. maltophilia.*[4,11] EMBLAVEO is the first ?-lactam/?-lactamase inhibitor combination for treating serious bacterial infections in adult patients caused by multidrug-resistant Gram-negative bacteria, including MBL-producing bacteria, approved for use in the EU.

EMBLAVEO was jointly developed with AbbVie. Pfizer holds the global rights to commercialize this therapy outside of the U.S. and Canada, where the rights are held by AbbVie. Development of EMBLAVEO was also supported by public-private partnerships between Pfizer and the U.S. Department of Health and Human Services; Administration for Strategic Preparedness and Response; Biomedical Advanced Research and Development Authority (BARDA) under OTA number HHSO100201500029C; and through the EU's Innovative Medicines Initiative (IMI) – a partnership between the EU and the European pharmaceutical industry – under a project called COMBACTE-CARE (Combatting Bacterial Resistance in Europe – Carbapenem Resistance). The COMBACTE-CARE consortium is a unique public-private collaboration that unites the knowledge and capabilities of leading drug-resistant bacterial infection experts and is supported by the COMBACTE pan-European clinical and laboratory networks.

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 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/.

Category: Prescription Medicines

Disclosure Notice

The information contained in this statement is as of April 22, 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 EMBLAVEO (aztreonam-avibactam), including its potential benefits, a marketing authorization granted by the European Commission, and planned regulatory submissions in other countries, 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 EMBLAVEO; 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 any drug applications may be filed in any other jurisdictions for EMBLAVEO; whether and when regulatory authorities in any such other jurisdictions where applications may be filed or pending may approve such applications, 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 whether EMBLAVEO 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 EMBLAVEO; the impact of COVID-19 on our 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, 2023 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.

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