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For Immediate Release

ADVANZ PHARMA receives positive CHMP opinion for EXBLIFEP® (cefepime/enmetazobactam)

- EXBLIFEP® demonstrated in a phase III clinical trial significant superiority in the primary composite endpoint of clinical cure and microbiological eradication over piperacillin/tazobactam in patients with complicated urinary tract infections caused by gram negative bacteria
- The antibiotic drug was originally developed by Allecra Therapeutics up to Phase III completion
- The Committee for Medicinal Products for Human Use (CHMP) has adopted a positive opinion and recommended granting a marketing authorization for EXBLIFEP®
- ADVANZ PHARMA will commercialise EXBLIFEP® across Europe once approved and continues its journey to strengthen its portfolio of innovative medicines in areas with high patient need

London, UK – 25/01/2024: - ADVANZ PHARMA Corp. Limited ("ADVANZ PHARMA" or "the Company"), a UK headquartered global pharmaceutical company with a strategic focus on speciality, hospital, and rare disease medicines in Europe, Canada, and Australia, today announced that the CHMP has adopted a positive opinion and recommended granting a marketing authorization for EXBLIFEP®, an antibiotic fixed-dose combination of cefepime and enmetazobactam. The CHMP's positive opinion will be referred to the European Commission, which will deliver a final decision in approximately two months.

ADVANZ PHARMA and Allecra Therapeutics have signed an exclusive license agreement under which ADVANZ PHARMA gains the rights to further develop and commercialize Allecra's proprietary antibiotic drug cefepime/enmetazobactam within the European Union, the United Kingdom, Switzerland, and Norway.

EXBLIFEP® demonstrated significant superiority in the primary composite endpoint of clinical cure and microbiological eradication in a phase III clinical trial over piperacillin/tazobactam in patients with complicated urinary tract infections caused by gram negative bacteria. The positive opinion includes intravenous use of

EXBLIFEP® for the treatment of adults' patients with complicated urinary tract infections (cUTI), including pyelonephritis; hospital-acquired pneumonia (HAP), including ventilator associated pneumonia (VAP); and the treatment of patients with bacteraemia that occurs in association with, or is suspected to be associated with, any of the infections listed.

EXBLIFEP® has been designed as a new antibiotic combination to combat the growing antimicrobial resistance in gram-negative bacteria.

About EXBLIFEP®

EXBLIFEP® is an intravenous antibiotic fixed-dose combination of enmetazobactam, a novel extended-spectrum-lactamase inhibitor belonging to the penicillanic acid sulfone class, with the 4th generation cephalosporin cefepime that enhances the efficacy of cefepime against resistant bacteria, including ESBL-producing pathogens.

EXBLIFEP® has shown promising in vitro activity against the more resistant beta-lactamase mutations OXA-48 and AmpC, which are increasing in Europe and for which there are few therapeutic alternatives.

The pivotal Phase III ALLIUM trial compared 1034 randomized patients receiving either cefepime 2 g/ enmetazobactam 0.5 g or piperacillin 4 g/ tazobactam 0.5 g every 8 h as 2 h continuous intravenous infusion in a multi-centre, randomized, controlled, double-blind, global study in 112 sites within 19 countries.

EXBLIFEP® demonstrated statistically significant superior overall treatment success (clinical cure combined with microbiological eradication) at test-of-care visit compared with piperacillin/tazobactam in cUTI, including AP, caused by Gram-negative pathogens (79.1% vs. 58.9%). Statistically significantly superior results were also observed among patients with infections caused by ESBL-producing pathogens (73.7% vs. 51.5%, respectively).

EXBLIFEP® demonstrated a tolerable safety profile, comparable to piperacillin/tazobactam. Treatment-related SAEs were reported in 0.2% of patients treated with EXBLIFEP® vs. 0.6% of patients treated with piperacillin/tazobactam.

About complicated urinary tract infections (cUTI)

cUTIs are serious, potentially life-threatening infections occurring in patients with an increased chance of complicated course. Overall, cUTIs account for approximately 19% of all healthcare-associated infections. The range of mortality rates of cUTI reported in the literature is very broad (2%–31%), as it is derived from the different compositions of included patients in terms of age, type of infection and comorbidities. cUTIs, including acute pyelonephritis, are defined as urinary tract infections ascending from the bladder

accompanied by local and systemic signs and symptoms (ie. fever, chills, malaise, flank pain, back pain), that occur in the presence of a functional or anatomical abnormality of the urinary tract or in the presence of catheterization, with treatment typically initiated by IV therapy in a hospital setting.

About acute pyelonephritis (AP)

AP is a bacterial infection causing inflammation of the kidneys and is one of the most common diseases of the kidney. Pyelonephritis occurs as a complication of an ascending urinary tract infection (UTI) which spreads from the bladder to the kidneys and their collecting systems.

About hospital acquired pneumonia and ventilated acquired pneumonia

HAP/VAP is the second most common nosocomial infection (after cUTI) and a leading cause of death from nosocomial infections in critically ill patients.

Hospital-acquired pneumonia (HAP) and ventilator-associated pneumonia (VAP) are lung infections caused by pathogens acquired during hospital stay, occurring ≥48 hours after hospital admission, and which were not incubating at the admission time. VAP is a subtype of HAP that develops in ICUs in patients who have been mechanically ventilated for ≥48 hours.

About ADVANZ PHARMA

Partner of choice in specialty, hospital, and rare disease medicines

ADVANZ PHARMA is a global pharmaceutical company with the purpose to improve patients' lives by providing and enhancing the specialty, hospital, and rare disease medicines they depend on. Our headquarters are in London, UK. We have commercial sales in more than 90 countries globally and have a direct commercial presence in more than 20 countries, including key countries in Europe, the US, Canada, and Australia, a Centre of Excellence in Mumbai, India, as well as an established global distribution and commercialisation partner network. ADVANZ PHARMA's product portfolio and pipeline comprises innovative medicines, specialty generics & biosimilars, and originator brands. Our products cover a broad range of therapeutic areas, including hepatology, gastroenterology, anti-infectives, critical care, endocrinology, oncology, CNS, and, more broadly, rare disease medicines. Our ambition is to be a partner of choice for the commercialisation of specialty, hospital, and rare disease medicines in Europe, Canada, and Australia. In line with our ambition, we are partnering with biopharma and development companies to bring medicines to patients. We can only achieve this due to our dedicated and highly qualified employees, acting in line with our company values of entrepreneurship, speed, and integrity.

For more information, please visit our Website or LinkedIn.

For media inquiries, please contact:
Courtney Baines
ADVANZ PHARMA
Tel: +44 7776 516979 **Email**: courtney.baines@advanzpharma.com

About Allecra Therapeutics

Allecra Therapeutics, founded in 2013, is a private, clinical-stage biopharmaceutical company developing novel therapies to combat antibiotic resistance by overcoming emergent resistance mechanisms. Lead product candidate, cefepime/enmetazobactam, has shown superiority over standard of care in patients with complicated urinary tract infections (cUTIs) in a randomized, controlled Phase 3 trial. The Company has significant patent protection covering proprietary enmetazobactam in major territories. Allecra's investors are: Forbion, Andera Partners, Delos Capital, Xeraya Capital, EMBL Ventures, and BioMedPartners. Allecra's wholly owned French subsidiary is a beneficiary of financial support from Bpifrance and the Région Alsace. Please visit www.allecra.com for further information and follow us on LinkedIn.

Contact:
For Allecra Therapeutics GmbH:
Andreas Kranzusch, Chief Financial Officer, ir@allecra.com

For media:
Gretchen Schweitzer, Trophic Communications, +49 172 8618540,allecra@trophic.eu