



Allecra Therapeutics and ADVANZ PHARMA Sign Exclusive License and Supply Agreement for Allecra’s Antibiotic Cefepime/enmetazobactam in Europe

- Allecra receives upfront, development and commercial milestone payments, in addition to double-digit royalties
- ADVANZ gains commercial rights for cefepime/enmetazobactam in the European Union, the United Kingdom, Switzerland, and Norway
- Cefepime/enmetazobactam has completed a Phase III clinical trial against standard of care in treating complicated urinary tract infection, including acute pyelonephritis¹

SAINT-LOUIS, France and WEIL AM RHEIN, Germany and LONDON, UK, January 13, 2022: ADVANZ PHARMA Corp. Limited ("ADVANZ PHARMA"), a specialty pharmaceutical company with a strategic focus on hospital medicines in Europe, and Allecra Therapeutics ("Allecra") today announced that the companies have signed an exclusive license agreement under which ADVANZ PHARMA gains the rights to develop and commercialize Allecra’s antibiotic drug candidate cefepime/enmetazobactam within the European Union, the United Kingdom, Switzerland, and Norway. In exchange for the exclusive license, Allecra will receive an upfront payment and development and sales milestones for cefepime/enmetazobactam, as well as double-digit tiered royalties. In addition, the two companies have signed a supply agreement under which Allecra will supply the cefepime/enmetazobactam finished product in the agreed upon territories. No further financial details have been disclosed.

“ADVANZ PHARMA is building a leadership position in Europe as a specialty pharmaceutical company and they are an ideal commercialization partner for Allecra as we advance toward regulatory submission for cefepime/enmetazobactam,” stated Andreas Kranzusch, Chief Financial Officer at Allecra Therapeutics. “This agreement, together with our license agreement with Shanghai Haini for commercialization in China, reflects the understanding that there remains a need worldwide to address the dangerous increase of resistance to standard-of-care antibiotics. The pandemic has only heightened this awareness.”

Graeme Duncan, Chief Executive Officer of ADVANZ PHARMA, commented: “The importance of antibiotics and the quest to find new agents to overcome the issue of increasing resistance cannot be underestimated.² As we continue to push forward with our goal to become the partner of choice for commercializing hospital medicines in Europe, this is a great addition to our anti-infectives portfolio, and will further help enhance choice and access for patients. We look forward to adding cefepime/enmetazobactam to our portfolio upon regulatory approval.”

Cefepime/enmetazobactam is a combination of enmetazobactam, a extended-spectrum β -lactamase inhibitor, combined with the 4th generation cephalosporin cefepime.^{3,4} Due to their efficacy and safety, β -Lactams are the most widely used class of antibiotics, referred to commonly as penicillins and related β -lactam classes of cephalosporins, and cephamycins, among other names.⁴ Due to the extensive use, a growing number of pathogens have become resistant to a wide range of β -lactam antibiotics, posing a growing risk in both developed and developing countries. In the US alone, Extended-Spectrum β -lactam Resistant Pathogens (ESBLs) have increased >50% over a 6-year period.⁵

The consummation of the licensing transaction is subject to regulatory approval and other customary conditions precedent.

About cefepime/enmetazobactam

Cefepime/enmetazobactam has been investigated in patients with complicated urinary tract infections (cUTIs) compared to current standard of care in a randomized, controlled, double-blind, global Phase 3 trial.¹ Based on the positive data readout, Allecra expects to submit for marketing approval in the U.S. and EU. Cefepime/enmetazobactam has been granted Qualified Infectious Disease Product and Fast Track designation by the U.S. Food and Drug Administration (FDA), which will provide five years additional market exclusivity and priority FDA review. The European Medicines Agency (EMA) has indicated that, due to the combination of enmetazobactam with the already-approved cefepime and in light of results obtained in an epithelial lining fluid penetration study with cefepime/enmetazobactam, Allecra Therapeutics is allowed to seek approval of cefepime/enmetazobactam for use in pneumonia, including hospital-acquired/ventilator-associated pneumonia (HAP/VAP), without conducting a Phase 3 study in this indication.

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 successfully completed a randomized, controlled, double-blind, global Phase 3 trial compared to standard of care in patients with complicated urinary tract infections (cUTIs), and the Company is preparing submissions for marketing approval in the U.S. and EU based on these results.¹ The Company has significant patent protection covering proprietary enmetazobactam in major territories. Allecra's investors include 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](#).

About ADVANZ PHARMA

ADVANZ PHARMA is a specialty pharmaceutical company with a strategic focus on hospital medicines in Europe. With an agile and experienced team, including direct sales, marketing and medical capability across many of Europe's major markets, the Company supplies, innovates and enhances the critical medicines patients depend on, ensuring continued patient access and improving health outcomes.

With its European network and its expertise in the anti-infectives and endocrinology therapy areas, ADVANZ PHARMA is an attractive partner when commercializing hospital medicines in Europe.

ADVANZ PHARMA has an operational headquarters in London, an operations centre of excellence in Mumbai, commercial affiliates in North America, Europe, and Australia, and an established global network of commercial partners throughout the rest of the world.

For more information please visit: <https://www.advanzpharma.com/> 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

For ADVANZ PHARMA Corp. Limited:**For media:**

Meral Nugent

Tel: +44 208 588 9086

Mobile: +44 7557 49 60 35

meral.nugent@advanzpharma.com

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