Allecra Therapeutics Submits New Drug Application to the U.S. FDA for EXBLIFEP® for the Treatment of Complicated Urinary Tract Infections

SAINT-LOUIS, France and WEIL AM RHEIN, Germany, June 27, 2023 - Allecra Therapeutics ("Allecra") announced today the submission of a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for cefepime/enmetazobactam, an antibiotic combination of the fourth generation cephalosporin cefepime with the proprietary beta lactamase inhibitor, enmetazobactam, for the treatment of complicated urinary tract infections (cUTIs). Upon approval, the antibiotic combination will be marketed under the trademark name, EXBLIFEP®. EXBLIFEP® has been designed to combat anti-microbial resistance in gram-negative bacteria, especially resistance mediated by Extended Spectrum Beta Lactamases (or ESBLs). The NDA submission is supported by results from Allecra's Phase 3 ALLIUM trial, which met criteria for non-inferiority and superiority compared to piperacillin/tazobactam in the primary composite outcome of clinical cure and microbiological eradication in patients with cUTIs.

"This filing marks the culmination of a journey that began ten years ago with the formation of Allecra by a syndicate of European venture capital interests. I am extremely proud of and thankful for our small yet dedicated team which has, since company inception, worked diligently to reach this critical milestone," said Iain Buchanan, Supervisory Board Member of Allecra Therapeutics.

EXBLIFEP® was granted Qualified Infectious Disease Product (QIDP) status, which can enable priority review from the FDA and enhanced market exclusivity for applications for medicines that, if approved, would provide critical improvements in the efficiency and safety of antibacterial and antifungal drugs to treat serious or life-threatening infections.

About EXBLIFEP® (cefepime/enmetazobactam)

Cefepime/enmetazobactam has been investigated in patients with complicated urinary tract infections (cUTIs) compared to piperacillin/tazobactam, a current standard of care, in a randomized, controlled, double-blind, global Phase 3 trial. Cefepime/enmetazobactam has already been submitted for Marketing Authorization Approval in Europe by Allecra's commercial partner, Advanz Pharma. The European Medicines Agency (EMA) has indicated that, in light of results obtained in an epithelial lining fluid penetration study, the company is eligible for approval of cefepime/enmetazobactam for use in hospital-acquired/ventilator-associated bacterial pneumonia.

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 has applied for marketing approval in the U.S. and, together with its partner, Advanz Pharma, in the EU based on these results. The company has significant patent protection covering the proprietary compound, 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.

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

For media:
Desmond James, Trophic Communications, +49 1516 7859086, allecra@trophic.eu