Allecra Therapeutics Announces U.S. FDA Approval for EXBLIFEP® for the Treatment of Complicated Urinary Tract Infections

--Company Receives Five-year Exclusivity Extension Through GAIN Act --

SAINT-LOUIS, France & WEILL AM RHEIN, Germany, February 27, 2024 - Allecra Therapeutics ("Allecra"), a biopharmaceutical company developing novel therapies to combat antibiotic resistance, announced today that the U.S. Food and Drug Administration (FDA) has approved EXBLIFEP® (cefepime/enmetazobactam), as a treatment for complicated urinary tract infections (cUTIs), including pyelonephritis, in patients 18 years and older. Allecra has also received a five-year marketing exclusivity extension from the FDA as part of the Generating Antibiotic Incentives Now Act (GAIN Act). The GAIN Act, enacted by the U.S. Congress, incentivizes the creation of new anti-infective therapeutics by providing benefits to manufacturers of Qualified Infectious Disease Products (QIDPs).

"Receiving FDA approval is a tremendous achievement for Allecra and a testament to the hard work and dedication of a small, yet highly focused team of individuals. I extend my sincere congratulations to my colleagues Omar Lahlou and Patrick Velicitat for their leadership and oversight throughout this whole process," said Iain Buchanan, Supervisory Board Member of Allecra Therapeutics. "As we continue our discussions with strategic partners for product launch in the U.S., we value the FDA's positive decision on EXBLIFEP®'s ability to address a critical unmet medical need for patients."

The FDA's approval of EXBLIFEP® was supported by a totality of clinical data that demonstrated EXBLIFEP® effectiveness against antimicrobial resistance in gram-negative bacteria, especially resistance mediated by both ESBL (Extended Spectrum Beta Lactamases) and AmpC. This included 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.

Allecra is the sole holder of a significant patent estate covering EXBLIFEP® in major territories with the GAIN Act extending Allecra's market exclusivity until 2032. Enmetazobactam was first discovered by Orchid Pharma and all rights outside India were assigned to Allecra Therapeutics in 2013. The company has since taken the sole responsibility for the international clinical and regulatory development of EXBLIFEP®. Allecra was founded through a strategic partnership formed by Nicholas Benedict, Stuart Shapiro and Edward Currie in conjunction with Orchid Chemicals and Pharmaceuticals Ltd. and Allecra lead investors, Andera Partners, Forbion and EMBL Ventures. The company has concluded exclusive license agreements for EXBLIFEP® with Shanghai Haini Pharmaceutical in Greater China and ADVANZ PHARMA in Europe.

About EXBLIFEP® (cefepime/enmetazobactam)

EXBLIFEP® (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. EXBLIFEP® 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. A positive opinion was received from the CHMP (The Committee for Medicinal Products for Human Use) in January 2024.

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, EXBLIFEP® (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). Based on these results, the company has achieved FDA marketing approval in the U.S. and, together with its partner, Advanz Pharma, have submitted for marketing approval in the EU. 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.

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