Allecra Therapeutics Announces Late-breaker Presentation of Phase 3 ALLIUM Trial with Cefepime-Enmetazobactam in cUTIs at IDWeek 2020

- Superiority of cefepime-enmetazobactam demonstrated in subgroups of patients with extended spectrum β-lactamase (ESBL)-producing baseline uropathogens.

SAINT-LOUIS, France and WEIL AM RHEIN, Germany, October 23, 2020 – Allecra Therapeutics today announced that summary data from the Phase 3 (ALLIUM) trial evaluating cefepime-enmetazobactam (FPE) compared to the first-line standard of care, piperacillin-tazobactam (PTZ), in complicated urinary tract infections (cUTI) are being presented at this week's IDWeek 2020.

The late-breaker oral presentation, "Cefepime-Enmetazobactam Demonstrates Superiority to Piperacillin-Tazobactam in a Subgroup of Patients with Complicated Urinary Tract Infections/Acute Pyelonephritis Caused by Extended Spectrum β-Lactamase-Producing *Enterobacterales*," is being given by Keith Kaye, M.D., MPH. Dr. Kaye's live talk will be held:

Session Title: Late Breaking Abstracts

Session Date: Saturday, October 24, 2020

Presentation Time: 10:20-10:30 AM EDT

Channel: 1

The replay will be available following the live event to all registrants. Click here for the abstract.

Keith Kaye M.D., MPH, Professor of Medicine and Director of Research for Infectious Diseases at University of Michigan, said, "ESBL-producing bacteria represent a growing threat around the globe and have led to increased carbapenem use and carbapenem resistance. These issues have created an urgent need for novel, therapeutic options for ESBL-producers." Explaining the potential significance of this new data from the ALLIUM Phase 3 study, Dr. Kaye commented: "The data presented today demonstrate that cefepime-enmetazobactam was superior to standard of care treatment and support the potential of cefepime-enmetazobactam as a first-line treatment in settings where ESBL-producers are prevalent. Importantly, cefepime-enmetazobactam represents a legitimate therapeutic alternative to carbapenems for the treatment of ESBL-producing bacteria."

As previously announced, the trial demonstrated superiority in its primary endpoint, with FPE showing a significant improvement over PTZ in the composite success outcome of clinical cure and microbiological

eradication at the test-of-cure visit[1]. The new data are from subgroup analyses of patients with ESBL-producing bacteria – those resistant to either FPE or PTZ and those not resistant to either treatment. In both analyses[1], FPE demonstrated superiority over PTZ.

In the trial, FPE was well tolerated, with 4.3% of patients reporting serious adverse events vs. 3.7 % with PTZ (0.2% vs. 0.6% assessed as drug related), suggesting a comparable safety profile to PTZ.

About the ALLIUM Trial

The ALLIUM trial was a multi-center, randomized, controlled, double-blind, global study that enrolled 1,034 patients. Patients received either cefepime-enmetazobactam (FPE) or piperacillin-tazobactam (PTZ) via intravenous infusion. The study involved 112 sites in 19 countries. The primary efficacy endpoint was defined as the composite success outcome of clinical cure (symptoms resolution) and microbiological eradication ($<10^3$ CFU/mL in urine culture) at the test-of-cure visit. The primary efficacy evaluation was performed in the microbiological modified intent-to-treat population (m-MITT) including patients infected with a Gram-negative pathogen deemed non-resistant to cefepime-enmetazobactam and piperacillin-tazobactam - was a prespecified 10% noninferiority margin with superiority to be tested in the event of confirmed noninferiority. Differences in treatment effects were assessed using two-sided, 95% stratified Newcombe confidence intervals.

About Cefepime-Enmetazobactam (FPE)

Cefepime-enmetazobactam (FPE) is a combination of enmetazobactam, a novel extended-spectrum β-lactamase inhibitor belonging to the penicillanic acid sulfone class, with the 4th generation cephalosporin cefepime. FPE 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 with already approved cefepime and in light of the epithelial lining fluid penetration study results obtained with the FPE combination, Allecra Therapeutics is allowed to seek approval of FPE for use in pneumonia, including hospital-acquired/ventilator-associated pneumonia (HAP/VAP), without conducting a Phase 3 study in the pneumonia indication.

About Complicated Urinary Tract Infections (cUTIs)

There are approximately 3.6 million patients with cUTIs in the U.S. requiring antibiotic therapy. cUTIs, including acute pyelonephritis, are defined as urinary tract infections ascending from the bladder accompanied by local and systemic signs and symptoms, including fever, chills, malaise, flank pain, back pain, and/or costo-vertebral angle pain or tenderness, 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.

[1] The efficacy evaluation was performed in the microbiological Modified Intent-to-Treat (m-MITT) population, including patients infected with a Gram-negative pathogen deemed non-resistant to cefepime.

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, and the Company is preparing submissions for marketing approval in the U.S. and EU based on these results. 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.

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