Allecra Announces Initiation of a Phase 2 Clinical Trial for its Novel Antibiotic to Treat Resistant Bacterial Infections

Allecra's novel b-*lactamase inhibitor AAI101, co-administered with the powerful* b-*lactam cefepime, is to be evaluated in patients for its potential to combat hospital-acquired, resistant Gram-negative infections*

Lörrach, Germany and Saint Louis, France – Allecra Therapeutics, a biopharmaceutical company dedicated to the development of novel antibiotics to combat drug-resistant bacterial infections, today announces initiation of a Phase 2 clinical trial to evaluate the efficacy and safety of the combination cefepime/AAI101 for treatment of complicated urinary tract infections (cUTI).

AAI101 is Allecra's novel, proprietary extended spectrum b-lactamase inhibitor which, when tested in combination with cefepime, has demonstrated excellent efficacy against certain resistant bacteria frequently encountered in hospitals.

The Phase 2 consists of a randomized, double-blind trial with active comparator conducted in up to 63 patients from 38 treatment centers across six European countries. The primary objective of the trial is to define the optimal dose of the combination cefepime/AAI101 delivered intravenously to patients with cUTI. Top line results are expected early in 2018.

The emergence of antibiotic resistance is acknowledged globally to be one of the most critical threats to public health. In the USA, the Centers for Disease Control and Prevention [CDC] have estimated[1] at least 2 million people each year acquire serious infections due to drug-resistant bacteria. In February 2017, the World Health Organization published its first-ever list of "priority pathogens"[2]. The "critical" or top priority was assigned to Gram-negative pathogens including ESBL-producing Enterobacteriacae, the key microbiological target for cefepime/AAI101.

---

1 Centers for Disease Control and Prevention, U.S. Department of Health and Human Services *Antibiotic Resistance Threats in the United States, 2013*

2 World Health Organization *Priority Pathogens List for R&D of New Antibiotics*, 27 February 2017

Nicholas Benedict, CEO and co-founder of Allecra Therapeutics said: “Emerging bacterial resistance leaves many hospitals in dire need of an effective replacement for empirically-used antibiotics. The ideal replacement for current empirical therapies should be devoid of potential to engender ever more dangerous types of antibiotic resistance. It appears that cefepime/AAI101 combats the most widespread form of Gram-negative bacterial resistance found in hospitals without promoting the emergence and spread of superbugs. An antibiotic with this profile should be a very useful addition to hospital physicians’ armamentarium against bacterial resistance.”

Prof. George Drusano, Professor of Medicine and Director of the Institute of Therapeutic Innovation at the University of Florida, member of Allecra’s Scientific Advisory Board, commented: “In early testing, it was shown that Allecra’s new β-lactamase inhibitor, AAI101, has potential for use in combination with cefepime to become an effective workhorse antibiotic. The combination overcomes much of the resistance we currently see towards the antibiotics we use most often.”

Prof. Patrice Nordmann, Head of the Molecular Microbiology Unit of the Department of Medicine at the University of Fribourg, Switzerland, another of Allecra’s Scientific Advisors and close partners, added: “The majority of Gram-negative bacterial resistance in hospitals is caused by dissemination of extended spectrum β-lactamases (ESBLs). The novel combination of cefepime and AAI101 so far has demonstrated excellent efficacy against bacteria expressing ESBLs, including those resistant to the leading antibiotic used for such infections, piperacillin/tazobactam.”

Cefepime/AAI101 for intravenous use is designated Qualified Infectious Disease Product (QIDP) by the United States Food and Drug Administration for the treatment of cUTIs, complicated intra-abdominal infections (cIAI), hospital-acquired bacterial pneumonia (HABP) and for ventilator-associated bacterial pneumonia (VABP).

- Ends -

For further information please contact
Allecra Therapeutics GmbH
Nicholas Benedict
+41 79 592 2005
info@allecra.com

About Allecra Therapeutics

Allecra is a clinical stage biopharmaceutical company in the European BioValley Life Sciences cluster located in the Upper Rhine valley encompassing northwest

Switzerland, southwest Germany and the Alsace Region of France. Allecra is focused on the development of novel antibiotics to combat multi drug-resistant Gramnegative infections. Allecra's mission is to contribute towards the global effort to combat bacterial resistance by developing new antibiotics which overcome emerging resistance mechanisms, thereby saving lives of patients whose infections may otherwise be inadequately treated. Allecra's wholly-owned French subsidiary is a beneficiary of financial support from the French public bank Bpifrance and from the Region Alsace. For more information on Allecra please visit www.allecra.com or email info@allecra.com.