



PRESS RELEASE
February 14th 2018

Allegra Therapeutics Announces Fast Track Designation for Lead Antibiotic in Resistant Infections

Supports Allegra's lead program in Phase 2 clinical trials to treat serious Gram-negative infections

Lörrach, Germany and Saint Louis, France – Allegra Therapeutics, a biopharmaceutical company dedicated to the development of novel antibiotics for the treatment of drug-resistant bacterial infections, announces today that the U.S Food and Drug Administration (FDA) has granted Fast Track designation for the company's lead product candidate AAI101 when given in fixed dose combination with the antibiotic cefepime, a powerful treatment for serious hospital-acquired Infections.

“With AAI101, Allegra is targeting one of the most frequently encountered bacterial resistance mechanisms seen in hospitals throughout the world, known as ESBLs. Fast Track designation for Allegra's lead product candidate AAI101 not only validates Allegra's efforts to combat the current antibiotic crisis, but also facilitates our planned Phase 3 clinical trial which is now expected to begin this summer” commented Nicholas Benedict, Allegra's Chief Executive.

Fast Track designation is intended to expedite the potential availability of a drug candidate to patients which, in the view of FDA, has the potential to treat a serious or life-threatening condition and to fulfill an unmet medical need.

Allegra's lead product candidate, AAI101, is a novel Extended Spectrum β -lactamase inhibitor designed to overcome resistance of typical Gram-negative hospital pathogens harboring Extended Spectrum β -lactamases (ESBLs). Cefepime/AAI101 is in Phase 2 clinical development. Cefepime/AAI101 is already granted Qualified Infectious Disease Product (QIDP) status and is now granted Fast Track designation for use in complicated urinary tract infections (cUTI), complicated intra-abdominal infections (cIAI) and hospital-acquired bacterial pneumonia/ventilator-associated bacterial pneumonia (HABP/VABP).



The Centers for Disease Control and Prevention [CDC] have estimated¹ that at least 2 million people each year acquire serious infections due to drug-resistant bacteria in the U.S. alone.

- Ends -

For further information please contact

Allegra Therapeutics GmbH

Nicholas Benedict

+41 79 592 2005

info@allegra.com

About Allegra Therapeutics

Allegra is a biopharmaceutical company established in 2013 in the European BioValley Life Sciences cluster located in the Upper Rhine valley encompassing northwest Switzerland, southwest Germany and the Alsace Region of France. Allegra is focused on the development of novel treatments to combat multi drug-resistant Gram-negative bacterial infections. Allegra's mission is to contribute towards the global effort to combat antibiotic resistance by developing new treatments which overcome emerging resistance mechanisms, thereby saving lives of patients whose infections may otherwise be inadequately treated. Allegra is supported by investors Forbion Capital Partners, Delos Capital, Edmond de Rothschild Investment Partners, Xeraya Capital, EMBL Ventures, BioMed Partners and Nicholas Benedict. Allegra's wholly-owned French subsidiary is a beneficiary of financial support from the French public bank Bpifrance and from the Région Alsace. For more information on Allegra please visit www.allegra.com or email info@allegra.com.

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