Antabio Receives QIDP Designation from the U.S. FDA for the Development of MEM-ANT3310, a Novel Broad-Spectrum Combination Therapy Targeting WHO's Priority Pathogens

QIDP is granted to Antabio's MEM-ANT3310 for major hospital indications including nosocomial pneumonia

Labège, France, May 6th, 2020. Antabio SAS, the biopharmaceutical company focused on developing a broad pipeline of antibacterial treatments against life threatening WHO critical priority pathogens, announced today that the U.S. Food and Drug Administration (FDA) has granted Qualified Infectious Disease Product (QIDP) designation to Antabio's MEM-ANT3310, a combination of meropenem (MEM) and the novel broad-spectrum serine beta-lactamase inhibitor ANT3310. QIDP was granted to MEM-ANT3310 for the treatment of complicated urinary tract infections (cUTI), hospital-acquired bacterial pneumonia (HABP), ventilator-associated bacterial pneumonia (VABP) and complicated intra-abdominal infections (cIAI).

ANT3310 is a novel, potent and specific inhibitor of bacterial Serine Beta-Lactamases (SBLs) currently in preclinical development, which displays excellent inhibitory activity against both KPC and OXA carbapenemases. It will be administered intravenously in conjunction with meropenem, for treating hospital-acquired infections caused by Gram negative pathogens, including those that are carbapenem-resistant, notably carbapenem-resistant *Enterobacteriaceae* (CRE) and carbapenem-resistant *A. baumannii* (CRAB), which are WHO Priority Pathogens. CRAB is spreading worldwide, accounting for more than 70% of *A. baumannii* in many countries, and it is one of the most common causes of hospital-acquired respiratory infections.

ANT3310 potentiates meropenem activity against CRAB in murine infection models and restores meropenem susceptibility in 95% of *A. baumannii* clinical isolates. By targeting both CRE and CRAB, as well as covering most *P. aeruginosa* strains, the MEM-ANT3310 combination is clearly differentiated from other β-lactam/β-lactamase inhibitor (BL/BLI) combinations in its broad activity against key multi-drug resistant Gram-negative pathogens commonly encountered in nosocomial infections. The ANT3310 program is in preclinical development.

The QIDP designation was created by the Generating Antibiotic Incentives Now (GAIN) Act implemented in 2012 to encourage the development of treatments for antibiotic-resistant organisms known to cause serious or life-threatening infections. The QIDP status provides MEM-ANT3310 with a five-year extension of data exclusivity provisions and eligibility for Fast Track Designation and Priority Review of its New Drug Application (NDA) for cUTI once submitted.

Carole Sable, Head of Clinical Development at Antabio said: "*We are pleased that the FDA recognized the potential of MEM-ANT3310 to address the expanding, global threat of multidrug-resistant Gram-negative*

infections in granting QIDP designation to the combination. BL/BLI combinations are a proven strategy to combat the most common mechanisms of resistance to beta lactam antibiotics. The activity against both CRAB and CRE provides the potential for MEM-ANT3310 to be an important addition to the therapeutic armamentarium".

Martin Everett, Chief Scientific Officer of Antabio said: "*The receipt of the QIDP designation is an important regulatory milestone for MEM-ANT3310, and recognizes the potential of this drug to address the critical unmet need of mixed-pathogen infections commonly encountered in complicated nosocomial indications. The inclusion of CRAB in its spectrum of activity addresses a huge global unmet medical need that is particularly urgent in China and Asia Pacific where CRAB infections (especially respiratory infections) are rising rapidly*."

This is Antabio's second program to receive QIDP status, following QIDP designation of its Metallo Beta-Lactamase Inhibitor ANT2681 for cUTI awarded in June 2019.

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About Antabio

Antabio is a private biopharmaceutical company developing novel antibacterial resistance-breakers to treat drug resistant infections in areas of highest unmet medical need. Antabio is developing a portfolio of three programs which address WHO critical priority pathogens, and which are eligible for QIDP and streamlined development:

SBLi Program. Preclinical best-in-class DBO serine ß-lactamase (SBL) inhibitor (ANT3310) to be combined with meropenem for the treatment of KPC- and OXA-producing CRE as well as carbapenem-*resistant Acinetobacter baumannii* (CRAB), which are widespread globally and for which better broad-spectrum inhibitors are required. Assigned QIDP status by FDA.

MBLi Program. Phase 1 ready novel metallo ß-lactamase (MBL) inhibitor (ANT2681) to be combined with meropenem for the treatment of MBL-producing carbapenem-resistant Enterobacteriaceae (CRE), e.g. NDM strains, which are particularly prevalent throughout China and the Asia Pacific region and for which no inhibitors are currently available. Assigned QIDP status by FDA.

PEi Program. CARB-X funded program to develop an inhibitor of Pseudomonas aeruginosa elastase virulence factor to be used as an adjunct to current treatments to limit the damage and enhance clearance of Pseudomonas lung infections in Cystic Fibrosis patients.

Antabio intends to work with partners to fully capitalize on the multiple value creating opportunities offered by its broad and innovative programs.

Antabio is led by an international team of experts focused on understanding and resolving the most urgent unmet medical needs in antimicrobial resistance.

Antabio is backed by Omnes Capital, BNP Paribas Développement, Sham Innovation Santé (managed and advised by Turenne Capital), iXO Private Equity, IRDI SORIDEC Gestion, Galia Gestion and Antabio's historical investor and former President of OM Pharma Christophe Ricard. Antabio has raised a total of €35.6 million to-date.

For more information visit our website www.antabio.com - from China, visit: https://cn.antabio.com/ - and Twitter @antabio

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