Antabio Receives QIDP Designation from the U.S. FDA for the Development of Its Metallo Beta-Lactamase inhibitor ANT2681

Labège, France, 21 June 2019. Antabio SAS, a private biopharmaceutical company developing novel antibacterial treatments focused on drug-resistant life-threatening infections, announced today that the U.S. Food and Drug Administration (FDA) has granted Qualified Infectious Disease Product (QIDP) designation to its Metallo Beta-Lactamase Inhibitor ANT2681 in combination with meropenem (MEM) for the treatment of complicated urinary tract infections (cUTI).

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-ANT2681 with a five-year extension of data exclusivity provisions under the Hatch-Waxman Act. The Antabio program is also eligible for Fast Track designation and priority review of its New Drug Application (NDA) for cUTI once submitted.

ANT2681 is a novel, potent and specific inhibitor of bacterial Metallo Beta-Lactamases (MBLs) currently under preclinical development. It will be administered IV with meropenem for treating hospital-acquired infections caused by carbapenem-resistant Enterobacteriaceae (CRE), including New Delhi Metallo Beta-Lactamase (NDM) producers that are spreading worldwide. ANT2681 potentiates meropenem activity against NDM-CRE strains in animal infection models and restores meropenem susceptibility in over 90% of NDM-producing clinical isolates of Enterobacteriaceae, including all clinically-relevant NDM variants from worldwide origin tested so far.

Carole Sable, Head of Clinical Development at Antabio said: “We are pleased that the FDA recognized the potential of MEM-ANT2681 and provided it with QIDP status. We look forward to working with the FDA to advance this program and make it available to patients suffering from multidrug-resistant enterobacterial infections, including NDM-CRE infections that are among the highest priorities for WHO”.

Marc Lemonnier, Chief Executive Officer of Antabio said: “The receipt of the QIDP designation is an important regulatory milestone for MEM-ANT2681, a drug that is addressing a critical unmet need. Antabio believes that this novel drug has the potential to address the emerging threat of NDM-CRE globally, including in Asia Pacific, and is seeking an Asian partner to facilitate development in that region.”

About Antabio

Antabio is a private French biopharmaceutical company developing a broad pipeline of novel antibacterial treatments focused on drug-resistant life-threatening infections. Antabio has built an international team of experts to understand and resolve the most urgent unmet medical needs of the antibacterial space. All Antabio’s programs address WHO critical priority pathogens and are eligible for streamlined development. For more information visit our website www.antabio.com (from China, visit: https://cn.antabio.com/)