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CARB-X funds Microbiotix to develop a novel oral antibiotic to treat multidrug-resistant gonorrhea

Microbiotix's new antibiotic targets the trans-translation pathway of the multidrug-resistant bacterium Neisseria gonorrhoeae

(BOSTON and WORCESTER, MA) – CARB-X is awarding Microbiotix, a US-based clinical-stage biopharmaceutical company in Worcester, MA, up to US\$2.86 million in non-dilutive funding to develop a new oral antibiotic to treat multidrug-resistant gonorrhea, a sexually transmitted disease caused by bacteria that have developed resistance to all but one existing antibiotic. If the project successfully achieves certain development milestones, Microbiotix will be eligible for an additional \$16 million in funding from CARB-X.

"Drug-resistant gonorrhea is a growing global health problem that can cause serious and sometimes fatal health issues in men and woman and that has the possibility of increasing the risk of contracting or giving HIV," said **Erin Duffy, Chief of Research and Development of CARB-X**, which is based at Boston University School of Law. "*Neisseria gonorrhoeae* has developed resistance to the effects of antibiotics, and in some cases, there is only one drug to which the bacteria are susceptible. Microbiotix's project features a novel approach to creating a new antibiotic and is in the early stages of development. If successful and approved for use in patients, it could represent tremendous progress in the treatment of gonorrhea and help curb the spread of drug-resistant bacteria."

Drug-resistant *N. gonorrhoeae* is identified by the World Health Organization as a 'priority' pathogen, and classified by the US Centers for Disease Control and Prevention (CDC) as an 'urgent public health threat' that requires aggressive action. The Microbiotix project represents a new approach to tackling the disease, by targeting and inhibiting the trans-translation pathway essential for the bacteria to grow and replicate.

"Important multidrug-resistant (MDR) pathogens remain a top priority of Microbiotix's R&D efforts. We are very pleased to once again be working with CARB-X to advance the development of inhibitors targeting the novel *trans*-translation pathway of multidrug resistant *Neisseria gonorrhoeae*," said **Terry Bowlin, PhD, President & CEO, Microbiotix**. "Proposed as a single dose oral therapy, this innovative program has great potential, not only to address the urgent threat posed by MDR *N. gonorrhoeae*, but also to address other sexually-transmitted infection (STI) pathogens commonly found as coinfections." This is the second Microbiotix project to be funded by CARB-X. Microbiotix is also funded by CARB-X to develop inhibitors of the Type III secretion system of *Pseudomonas aeruginosa* for the treatment of pneumonia.

Spread of drug-resistant gonorrhea a growing problem

Gonorrhea is spread by sexual contact, and infection can occur in the genitals, rectum, and throat. The WHO estimates that about 78 million people a year are infected with gonorrhea; roughly 1.14 million of those infections occur in the US, of which an estimated 550,000 involve drug-resistant bacteria. Left untreated, gonorrhea can cause pelvic inflammatory disease and infertility in women, and sterility in men. Infection increases a person's risk of contracting HIV. Babies born to an infected woman can develop blindness.

Partnership driving antibacterial innovation

CARB-X is investing up to \$500 million in antibacterial R&D between 2016-2021. The goal is to support projects through the early phases of development through Phase 1, so that they will attract additional private or public support for further clinical development and approval for use in patients.

CARB-X is a consortium led by Boston University and funded by a global partnership. The CARB-X portfolio is the world's largest antibacterial development portfolio with 38 projects in five countries. Since its launch in 2016, CARB-X has announced 59 awards exceeding \$198.46 million, with additional funds committed if project milestones are met, to accelerate the development of antibacterial products. These funds are in addition to investments made by the companies themselves. The CARB-X pipeline will continuously evolve, as projects progress and others fail for a variety of reasons.

About antibiotic resistance and need for innovative antibiotics

Antibiotics are lifesaving drugs that underpin almost every aspect of modern medicine. As bacteria become more and more resistant to conventional antibiotics, common medical procedures such as joint replacement surgery, childbirth, chemotherapy and dialysis become increasingly risky. Antibiotic resistance indiscriminately affects people of all ages and nationalities. There is an urgent need for innovative, novel classes of antibiotics and a growing consensus that new economic models are needed to stimulate investment in innovation.

According to the WHO, an estimated 700,000 people die each year worldwide from drugresistant bacterial infections, including 35,000 in the US and 33,000 in Europe.

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represent the official views of the HHS Office of the Assistant Secretary for Preparedness and Response, or other CARB-X funders.

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About CARB-X

<u>Combating Antibiotic-Resistant Bacteria Biopharmaceutical Accelerator (CARB-X)</u> is a global non-profit partnership dedicated to accelerating early development antibacterial R&D to address the rising global threat of drug-resistant bacteria. CARB-X is led by Boston University and funding is provided by the <u>Biomedical Advanced Research and Development</u> <u>Authority</u> (BARDA), part of the Office of the Assistant Secretary for Preparedness and Response (ASPR) in the US Department of Health and Human Services , the <u>Wellcome Trust</u>, a global charity based in the UK working to improve health globally, <u>Germany's Federal Ministry of</u> <u>Education and Research (BMBF)</u>, the <u>Bill & Melinda Gates Foundation</u>, and with in-kind support from <u>National Institute of Allergy and Infectious Diseases</u> (NIAID), part of the US National Institutes of Health (NIH). CARB-X is investing up to \$500 million from 2016-2021 to support the development of innovative antibiotics and other therapeutics, vaccines, and rapid diagnostics . CARB-X supports the world's largest and most innovative pipeline of preclinical products against drug-resistant infections. CARB-X is headquartered at Boston University School of Law. <u>https://carb-x.org/</u>. Twitter @CARB_X.

About Microbiotix

Microbiotix is a Worcester, MA-based clinical-stage biopharmaceutical company focused on the discovery and development of novel treatments that target serious infectious diseases. Microbiotix's lead product candidate, MBX-400, a novel, potent nucleoside analog inhibitor, has completed Phase 1 clinical studies for cytomegalovirus-related infections in transplant recipients. An ophthalmic formulation of MBX-400 is in preclinical development as a first-inclass antiviral for adenoviral conjunctivitis. <u>www.microbiotix.com</u>

About BARDA and NIAID

The US Department of Health and Human Services works to enhance and protect the health and well-being of all Americans, providing for effective health and human services and fostering advances in medicine, public health, and social services. Within HHS, ASPR's mission is to save lives and protect Americans from 21st century health security threats. ASPR leads the nation's medical and public health preparedness for, response to, and recovery from disasters and public health emergencies. BARDA provides a comprehensive, integrated, portfolio approach to the advanced research and development, innovation, acquisition, and manufacturing of medical countermeasures – vaccines, drugs, therapeutics, diagnostic tools, and non-pharmaceutical products for public health emergency threats. These threats include chemical, biological, radiological, and nuclear agents, pandemic influenza, and emerging infectious diseases. NIH is the primary US federal agency conducting and supporting basic, clinical, and translational medical research, and is investigating the causes, treatments, and cures for both common and rare diseases. NIAID conducts and supports research — at NIH, throughout the United States, and worldwide — to study the causes of infectious and immune-mediated diseases, and to develop better means of preventing, diagnosing and treating these illnesses.

About Wellcome Trust

Wellcome exists to improve health for everyone by helping great ideas to thrive. We're a global charitable foundation, both politically and financially independent. We support scientists and researchers, take on big problems, fuel imaginations and spark debate. The Wellcome Trust is a charity registered in England and Wales, no. 210183. Its sole trustee is The Wellcome Trust Limited, a company registered in England and Wales, no. 2711000 (whose registered office is at 215 Euston Road, London NW1 2BE, UK)

About **BMBF**

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About Boston University

Founded in 1839, Boston University is an internationally recognized institution of higher education and research. With more than 33,000 students, it is the fourth-largest independent university in the United States. BU consists of 17 schools and colleges, along with a number of multi-disciplinary centers and institutes integral to the University's research and teaching mission. In 2012, BU joined the Association of American Universities (AAU), a consortium of 62 leading research universities in the United States and Canada. For further information, please contact Jeremy Thompson at jeremy22@bu.edu. www.bu.edu.