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INTERNATIONAL PARTNERSHIP ESTABLISHED TO TACKLE ANTIMICROBIAL RESISTANCE

(LONDON/WASHINGTON, D.C.) - The U.S. Department of Health and Human Services (HHS), the Wellcome Trust of London, the AMR Centre of Alderley Park, Cheshire in the United Kingdom and Boston University School of Law today announced the establishment of one of the world's largest public-private partnerships focused on tackling antibiotic resistance, an emerging modern threat to public health worldwide.

The Combating Antibiotic Resistant Bacteria Biopharmaceutical Accelerator, or CARB-X (www.carbx.org), brings together leaders in industry, philanthropy, government and academia with the aim of rejuvenating the antimicrobial pipeline for the next 25 years.

The Biomedical Advanced Research Authority (BARDA), within HHS' Office of the Assistant Secretary for Preparedness and Response (ASPR), will provide \$30 million in research and development funding through CARB-X during the first year and up to \$250 million over five years.

The AMR Centre, a public-private initiative formed in February 2016 to drive the development of new antibiotics and diagnostics, aims to provide \$14 million to support CARB-X projects in year one and up to \$100 million over five years.

The Wellcome Trust, a global charitable foundation focused on biomedical research, will contribute further funding and its expertise in overseeing projects of this kind.

CARB-X grew out of President Obama's 2015 Combating Antibiotic Resistant Bacteria (CARB) initiative and will address several goals laid out in the US Federal CARB National Action Plan.

"Our hope is that the combination of technical expertise and life science entrepreneurship experience within the CARB-X's life science accelerators will remove barriers for companies pursuing the development of the next novel drug, diagnostic, or vaccine to combat this public health threat," said Joe Larsen, Ph.D., acting BARDA deputy director. "In the same way BARDA's investment model has proven successful in advancing countermeasures through late-stage development, we believe this international partnership can identify promising candidates in the early stages of development that may offer treatment options for drug resistant bacterial infections."

In 2014 the UK government and the Wellcome Trust asked economist Jim O'Neill to analyze the global problem of antimicrobial resistance and propose concrete actions to tackle it internationally. His final report, published in May 2016, called for concerted global effort to

boost the supply of new antibiotics, and to develop rapid diagnostics to allow existing drugs to be used more sparingly. CARB-X will play a significant role in answering this call.

"Drug-resistant infections are already costing lives all over the world. Many drugs that we have too often taken for granted no longer work, presenting one of the biggest threats to our future global health and economic security," said Dr. Jeremy Farrar, Director of the Wellcome Trust. "A problem of this scale can only be tackled through coordinated international effort to curb our massive over use of existing antibiotics, and to accelerate the development of new ones. I hope our new transatlantic partnership marks the beginning of a wider global effort to prevent untreatable bacterial infections from claiming millions of lives."

CARB-X aims to deliver a growing portfolio of promising new antibiotics, diagnostics and vaccines, to tackle the threat posed by untreatable bacterial infections. The international partnership will support a suite of products through early preclinical development to a stage where they can be taken forward by private or public investment.

"CARB-X is one of the most important steps yet in terms of rethinking how we deal with AMR and it will have an impact around the world," said Dr. Peter Jackson, Steering Group Chairman of the AMR Centre. "At the AMR Centre we share the same goal of accelerating a new pipeline of treatments and diagnostics by working on new drug development programs in our own labs as well as with other collaborating organizations, in particular providing support to small and medium-sized businesses and research institutes which have exciting new approaches to AMR."

Led by executive director and principal investigator Kevin Outterson, the N. Neal Pike Scholar in Health & Disability Law and Professor of Law at Boston University, the CARB-X partners will pool their broad scientific, technical, business and legal expertise to help grantees navigate the maze of regulatory steps, studies and data collection required for new drugs and other products to gain approval by US and/or European regulators.

"The grant to establish the CARB-X project, with Kevin Outterson of the School of Law as executive director, is a major milestone for Boston University," said Boston University President Dr. Robert A. Brown. "That the leadership for this collaboration among very distinguished public and private entities comes from Boston University is testament to our range and depth as a research university. Most of us understand the arms race that is ongoing between the natural evolution of bacteria harmful to humans and our development of the drugs that combat them. The CARB-X project will accelerate drug development in this critical race with nature."

The CARB-X partners include:

- The Biomedical Advanced Research and Development Authority (BARDA), within the HHS Office of the Assistant Secretary for Preparedness and Response (ASPR) who will draw on its extensive experience of successfully advancing promising medical

countermeasures through late-stage development and provide \$30 million during the project's first year and up to \$250 million during the five-year program;

- Wellcome Trust is a global charitable foundation in London, UK. They are a major funder of biomedical research with significant experience in infectious diseases and investment in early stage antibiotic R&D. In addition to providing funding, Wellcome will bring expertise in overseeing high quality international research projects.
- AMR Centre is a public-private initiative based in Alderley Park, Cheshire, UK that supports development of new antibiotics and diagnostics and will provide funding along with business mentoring and research support.
- Boston University School of Law in Boston, Massachusetts, will host the CARB-X executive team which will include experts with decades of experience in antibiotic drug development, including John Rex, Senior Vice President at Astra Zeneca. Starting January 1, 2017, Barry Eisenstein (formerly of Cubist and currently at Merck) will join CARB-X.
- The National Institutes of Health's National Institute of Allergy and Infectious Disease (NIAID), which leads the U.S. government in determining the causes of infectious and immune-mediated diseases and developing better means of preventing, diagnosing and treating these illnesses. NIAID will provide in-kind services, including preclinical services, to projects that CARB-X supports. NIAID also is providing technical support for CARB-X from their internal subject matter experts in early stage antibiotic drug discovery and product development;
- MassBio in Cambridge, as an extension of the successful MassCONNECT program, and California Life Sciences Institute (CLSI) in the Bay Area will provide world-class business support and mentoring services to innovative product developers selected for funding. The two accelerators will also share best practices with the Wellcome Trust and AMR Centre, expanding the scope of business support services globally;
- The Broad Institute of MIT and Harvard in Cambridge, Massachusetts will host a new inter-disciplinary Collaborative Hub for Early Antibiotic Discovery. This hub, aimed at early drug discovery, will work with multiple academic programs to advance promising antibiotic candidates that the CARB-X initiative can pursue.
- RTI International will provide technical and regulatory support services to product developers in the partner accelerators as well as build and run the computing systems to identify, track and monitor all research programs, including a real-time dashboard

management information systems. RTI will evaluate all CARB-X operations to identify and share best practices across all partners and supporting continuous quality improvement.

Beginning in September, CARB-X will begin reviewing applications to determine the most promising products to fund. Decisions will be made by the Scientific Advisory Board, with input from the agencies, including BARDA and NIAID, and the funders. Applicants should check the website (www.carb-x.org) for updates.

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