CARB-X FUNDS SPECIFIC DIAGNOSTICS TO SUPPORT THE DEVELOPMENT OF A RAPID ACCURATE TEST TO DIAGNOSE LIFE-THREATENING DRUG-RESISTANT INFECTIONS IN THE BLOOD

Specific's antibiotic susceptibility testing system promises accurate drug susceptibility and identification of superbugs within 4 hours of a positive blood sample, reducing the chance of life-threatening sepsis and other urgent complications of blood infections

04.03.2018 | CARB-X is awarding Specific Diagnostics of Mountain View, CA, up to $1.7 million, with the possibility of up to $1.7 million more based on achievement of project milestones, to support the development of the company's antibiotic susceptibility testing (AST) system, which could be a game-changer in the way drug-resistant infections are diagnosed and treated, resulting in lower health costs and fewer deaths.

"Specific Diagnostics' project is an example of cutting edge technology that could potentially speed up and change the way life-threatening infections are diagnosed and treated," said Kevin Outterson, Executive Director of CARB-X. "The world urgently needs new diagnostics, antibiotics, vaccines and other products to protect us from current and emerging drug-resistant bacteria. All the projects in the Powered by CARB-X portfolio are in the early stages of development, but if successful, they offer great potential in the fight against drug-resistant bacteria and in saving lives around the world."

"We are honored and inspired to have been selected by CARB-X, which has rapidly emerged as among the world's leading funders of solutions for drug resistant infection," said Paul A. Rhodes, Ph.D., Specific's CEO. "Our new instrument determines phenotypic antibiotic susceptibility with hours of blood infection, and CARB-X's support affirms the importance of that capability and helps us bring it to clinics around the globe for evaluation in 2018."

Rapid diagnostics essential to winning the fight against drug resistant bacteria

CARB-X funding will support the development and testing of Specific's product, which is designed to quickly detect the emitted volatile molecules that are the first sign of bacterial growth in the blood and to determine which antibiotic is most suited to kill the bacteria.

Rapid diagnostics provide quick answers to doctors and can take the guesswork out of treatment decisions in the first critical few hours and days of illness, reducing the chance of life-threatening sepsis and other urgent complications of blood infections. Currently, it can take days of laboratory testing to diagnose a lethal bacterial infection in the bloodstream. Faster diagnosis will enable medical staff to treat the patient quickly with appropriate antibiotics.

Specific's project brings to four the number of diagnostics in the Powered by CARB-X portfolio, three of which focus on rapid diagnosis of bloodstream infections.

Expanding portfolio

The CARB-X portfolio is the world's largest and most scientifically diverse portfolio of early development antibacterial projects with 29 projects including antibiotics and other therapeutics, vaccines and diagnostics to

respond to the threat of drug-resistant bacteria. CARB-X, which stands for Combating Antibiotic Resistant Bacteria Biopharmaceutical Accelerator, funds projects in 7 countries and is working to expand its pipeline with the best science from around the world.

Since it was established in 2016, CARB-X has announced awards totaling $75.6 million, plus an additional $90.7 million if project milestones are met, to accelerate the development of antibiotics and other products. These funds are in addition to investments made by the companies themselves.

New antibiotics, diagnostics and other products are needed urgently to treat bacteria that are becoming increasingly resistant to existing antibiotics. According to the World Health Organization (WHO), an estimated 700,000 people die each year worldwide from bacterial infections. According to the CDC, in the United States alone, an estimated 23,000 people die each year from drug-resistant bacterial infections.

Partnership to drive antibacterial innovation

CARB-X is a partnership between the UK charity Wellcome Trust, the US Department of Health and Human Services Biomedical Advanced Research and Development Authority (BARDA), part of the Office of the Assistant Secretary for Preparedness and Response (ASPR), and the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH). The CARB-X funding announced today is in addition to previously announced support from NIAID for development of the Specific's microorganism identification and antibiotic susceptibility diagnostics.

CARB-X funding is part of a commitment of up to $455m by the US government and Wellcome Trust from 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. The scope of CARB-X funding is restricted to projects that target drug-resistant bacteria highlighted on the 'Antibiotic Resistant Threats in the United States' report published by the Centers for Disease Control and Prevention (CDC) in 2013 or the Priority Bacterial Pathogens list published by the World Health Organization (WHO) in 2017– with a priority on those pathogens deemed Serious or Urgent on the CDC list or Critical or High on the WHO list.

Responsible use of existing antibiotics and equitable access, particularly in low-income countries where need is greatest, is also vital to addressing the global health problem. Both are a condition of CARB-X funding.

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About CARB-X

CARB-X is the world's largest public-private partnership devoted solely to accelerating early development antibacterial R&D. Funded by ASPR/BARDA and Wellcome Trust, with in-kind support from NIAID, CARB-X is investing up to $455 million from 2016-2021 to support innovative antibiotics and other therapeutics, vaccines, rapid diagnostics and devices to treat drug-resistant bacterial infections. CARB-X focuses on high priority drug-resistant bacteria, especially Gram-negatives. CARB-X operates through Boston University. Other partners include RTI International, the Broad Institute of Harvard and MIT, MassBio, and the California Life Sciences Institute (CLSI). http://www.carb-x.org/.

About Specific Diagnostics

Specific Diagnostics has developed *in vitro* diagnostic systems for the detection and identification of microorganisms while they grow in culture. The company's unique patented technology leverages a low-cost printed chemical sensor array, enabling diagnostic products that simplify workflow and speed time-to-answer at low cost. During growth in culture, bacteria emit organism-specific small molecule metabolite mixtures. Specific's products utilize inexpensive printed sensor arrays to obtain a profile of such mixtures, enabling detection of growth, antibiotic efficacy, and microorganism ID with simple, automated, low-cost instruments and disposables. Accuracies of minimum inhibitory concentration (MIC) determination meet those of gold standard broth microdilution methods, but with results obtained within four hours of a positive blood culture, directly from a diluted positive blood sample. The system will streamline lab workflow, reduce costs, and substantially shorten the time from sample arrival to selection of effective therapy, saving patients faced with fast-moving and deadly drug-resistant blood infections. Specific is located in Mountain View, California. For more information, visit www.specificdx.com, or email us at press@specificdx.com.

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 HHS, ASPR and NIH

HHS is the principal federal agency for protecting the health of all Americans and providing essential human services, especially for those who are least able to help themselves.

ASPR's mission is to save lives and protect Americans from 21st century health security threats. ASPR leads the federal public health and medical preparedness and response to disasters and other emergencies, on behalf of the Secretary of HHS. Within ASPR, BARDA provides a comprehensive integrated portfolio approach to the advanced research and development, innovation, acquisition, and manufacturing of vaccines, drugs, therapeutics, diagnostic tools, and non-pharmaceutical products for public health emergency threats. These threats include chemical, biological, radiological, and nuclear threat agents, pandemic influenza, and emerging infectious diseases.

NIAID is one of the 27 Centers and Institutes of the National Institutes of Health (NIH) a component of the U.S. Department of Health and Human Services. NIH is the nation's medical research agency, and is the primary 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. For more information about NIH and its programs, visit www.nih.gov. News releases, fact sheets and other NIAID-related materials are available on the NIAID website: https://www.niaid.nih.gov.

About Boston University

A leading research university with over 33,000 undergraduate and graduate students from more than 130 countries, nearly 10,000 faculty and staff, 17 schools and colleges, and 250 fields of study. Boston University is consistently ranked among the world's best research universities and is a member of the American Association of Universities. For further information, see www.bu.edu or contact Ann Comer-Woods anncomer@bu.edu.

About the Broad Institute of MIT and Harvard

Broad Institute of MIT and Harvard was launched in 2004 to empower this generation of creative scientists to transform medicine. The Broad Institute seeks to describe all the molecular components of life and their connections; discover the molecular basis of major human diseases; develop effective new approaches to diagnostics and therapeutics; and disseminate discoveries, tools, methods, and data openly to the entire scientific community. Founded by MIT, Harvard, Harvard-affiliated hospitals, and the visionary Los Angeles philanthropists Eli and Edythe L. Broad, the Broad Institute includes faculty, professional staff, and students from throughout the MIT and Harvard biomedical research communities and beyond, with collaborations spanning over a hundred private and public institutions in more than 40 countries worldwide. For further information about the Broad Institute, http://www.broadinstitute.org. In support of CARB-X, the Broad Institute created the Collaborative Hub for Early Antibiotic Discovery (CHEAD), which serves an interdisciplinary center that partners with academic investigators engaged in antibiotic development and/or resistance research to accelerate their early-stage, small molecule therapeutics toward Investigational New Drug (IND) application.

About MassBio

MassBio is a not-for-profit organization founded in 1985 that represents and provides services and support for the world's leading life sciences supercluster. MassBio is committed to advancing Massachusetts' leadership in the life sciences to grow the industry, add value to the healthcare system and improve patient lives. Representing 1000+ biotechnology companies, academic institutions, disease foundations and other organizations involved in life sciences and healthcare, MassBio leverages its unparalleled network of innovative companies and industry thought leaders to advance policy and promote education, while providing member programs, events, industry information, and services. Learn more at MassBio

About the California Life Sciences Institute (CLSI)

The mission of the California Life Sciences Institute (CLSI) is to maintain California's leadership in life sciences innovation through support of entrepreneurship, education and career development. Located in the birthplace of biotechnology, CLSI strives to ensure that the economic and intellectual power of the region's life sciences industry and its employees remains strong. By maintaining its focus on entrepreneurship, education and career development programs, CLSI supports the foundations of innovation that have made California home to the world's most prominent life sciences ecosystem. As a non-profit 501(c)(3), CLSI's objectives are met through collaborations, partnerships, and the generosity of individuals, sponsors and foundations. CLSI is a member of the CARB-X consortium, serving as an accelerator. Learn more at http://califesciencesinstitute.org.

About RTI International

RTI International is an independent, nonprofit research institute dedicated to improving the human condition. Clients rely on us to answer questions that demand an objective and multidisciplinary approach—one that integrates expertise across the social and laboratory sciences, engineering, and international development.

We believe in the promise of science, and we are inspired every day to deliver on that promise for the good of people, communities, and businesses around the world. For more information, visit www.rti.org.