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Iterum Gains Important Support for Development of Novel Oral Antibiotic, Sulopenem

CARB-X selects Iterum's sulopenem to receive \$1.5 million investment

Funding recognizes urgent need for new therapies against resistant bacteria

DUBLIN, IRELAND –July 25, 2017 – Iterum Therapeutics Limited, a clinical-stage pharmaceutical company focused on the development and commercialization of drugs to treat patients with infectious diseases, today confirmed a \$1.5 million award to support the development of its novel antibiotic sulopenem.

The investment comes from the world's largest public-private partnership devoted to early stage antibacterial R&D. CARB-X, which stands for Combating Antibiotic Resistant Bacteria Biopharmaceutical Accelerator, is backed by the US Government – through the Biomedical Advanced Research and Development Authority (BARDA) and the National Institute of Allergy and Infectious Diseases (NIAID) – and the UK charity Wellcome Trust. It was launched in July 2016 to address the gap in antibiotic research and development and innovations to improve diagnosis and treatment of drug-resistant infections.

"This award is a significant validation of our approach and our scientific program," said Corey Fishman, CEO of Iterum. "BARDA, NIAID and Wellcome expect CARB-X to make careful, data-driven decisions, selecting innovative programs that accelerate the search for new ways to combat antibiotic-resistant bacteria."

"Antibiotic resistance is a very serious and growing threat," said Dr. Michael Dunne, who heads Iterum's R&D. "Our development program is focused on addressing the urgent need for new therapies, targeted at patients who require them most. We believe an effective oral therapy will have significant clinical value in both hospitals and in communities where resistance is rapidly increasing."

Iterum's sulopenem is under development as a novel oral and intravenous antibiotic for the treatment of Gram-negative multi-drug resistant infections. The company anticipates the initiation of Phase 3 clinical studies in 2018.

[Sulopenem](#) has demonstrated broad-spectrum in vitro activity against extended spectrum β -lactamase producing and quinolone-resistant Gram-negative pathogens that are increasingly prevalent in both the inpatient and outpatient settings. These resistant pathogens are common causative agents of the initial target indications for sulopenem. These include uncomplicated urinary tract infections, complicated urinary tract infections and complicated intra-abdominal infections (uUTI, cUTI and cIAI).

The new funding will support ongoing research including:

- Studies of gram negative bacteria and their resistance to existing antibiotics.
- The potential effectiveness of sulopenem to eliminate those resistant pathogens in mechanistic and surveillance studies.
- A phase 1 study to measure the pharmacokinetics of different formulations of sulopenem.
- Refinements in the process of the large-scale manufacturing of sulopenem.

Kevin Outterson, Executive Director of CARB-X and Professor of Law at Boston University said, “Drug-resistant infections are complex and developing new antibiotics challenging, timely and costly. But restoring the R&D pipeline is vital to address the seriously increasing threat of superbugs which have become resistant to existing drugs. This is a global problem and CARB-X is a critical part of the global solution. We are looking to support the best potential new treatments and diagnostics across the world. We are especially pleased that today’s awards mean we are now supporting scientists in six countries. The projects offer exciting potential. But we need greater global support from governments, industry and civil society to get the new treatments the world urgently needs.”

About Iterum Therapeutics Limited

Iterum Therapeutics Limited is an Irish clinical-stage pharmaceutical company dedicated to developing differentiated anti-infectives aimed at combatting the global crisis of multi-drug resistant pathogens to significantly improve the lives of people affected by serious and life-threatening diseases around the world. Iterum is advancing its first compound, sulopenem, a novel penem anti-infective compound with oral and IV formulations in an IV only class of antibiotics that has demonstrated potent in vitro activity against a wide variety of gram-negative, gram-positive and anaerobic bacteria resistant to other antibiotics. Iterum has received QIDP designations for its oral and IV formulations for the treatment of uUTI, cUTI and cIAI. Iterum is led by a highly experienced team and backed by a blue-chip venture capital syndicate. For more information, please visit <http://www.iterumtx.com>.

About CARB-X

CARB-X is the world’s largest public-private partnership devoted to early stage antibacterial R&D. Funded by BARDA and Wellcome Trust, with in-kind support from NIAID, we will spend up to \$455 million from 2017-2021 to support innovative products from ‘hit-to-lead’ stage through to Phase 1 clinical trials. CARB-X focuses on high priority drug-resistant bacteria, especially Gram-negatives. CARB-X is a charitable global public-private partnership led by Boston University. Other partners include the Broad Institute of Harvard and MIT, MassBio, the California Life Sciences Institute and RTI International. For more information, please visit <http://www.carb-x.org> and follow us on Twitter [@CARB_X](https://twitter.com/CARB_X)

Media Contact:

Stephen Lederer
 Stephen Lederer Communications
 860 501 5058
stephen.lederer@ymail.com