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Iterum Therapeutics Provides Update on Phase 3 Clinical Trials of Sulopenem in Complicated Urinary Tract Infection (cUTI) and Uncomplicated Urinary Tract Infection (uUTI)

Topline results from uUTI and cUTI clinical trials to be announced in Q2 2020

Iterum Therapeutics maintaining business operations amid COVID-19 public health crisis

DUBLIN, Ireland and CHICAGO, March 31, 2020 (GLOBE NEWSWIRE) -- Iterum Therapeutics plc (Nasdaq: ITRM), a clinical-stage pharmaceutical company focused on developing next generation oral and IV antibiotics to treat infections caused by multi-drug resistant pathogens in both community and hospital settings, today announced that it anticipates reporting topline results from its **Su**lopenem for **R**esistant **E**nterobacteriaceae (SURE) 1 clinical trial in uUTI and SURE 2 clinical trial in cUTI in the early part of the second quarter of 2020.

As previously announced, patient enrollment and treatment for SURE 1 and SURE 2 clinical trials were completed in early 2020.

“Despite the COVID-19 pandemic, we are working closely with our partners as they complete the processing of data and wrap-up the final steps necessary to enable us to report topline results from these clinical trials as close as possible to our original timeline of around the end of the first quarter,” said Corey Fishman, Chief Executive Officer of Iterum Therapeutics. “We look forward to sharing results in the near-term and remain confident in the potential of sulopenem to become the first and only oral and IV penem antibiotic treatment option to help address the ongoing, global threat caused by multi-drug resistant infections impacting both hospital and community settings.”

About Sulopenem

Sulopenem, a novel penem anti-infective compound with oral and IV formulations, has demonstrated potent *in vitro* activity against a wide variety of gram-negative, gram-positive and anaerobic bacteria resistant to other antibiotics. If approved, sulopenem will help address the significant clinical and economic need for new oral antibiotics that enable the avoidance of hospitalization or facilitate early hospital discharge by providing continuity-of-care step-down therapy. The safety profile of IV sulopenem has been documented in a Phase 2 program. Oral and IV sulopenem are being evaluated in pivotal Phase 3 clinical trials for uncomplicated urinary tract infections, complicated urinary tract infections and complicated intra-abdominal infections.

The U.S. Food and Drug Administration (FDA) has granted Special Protocol Agreements (SPA) and Qualified Infectious Disease Product (QIDP) designations for oral and IV sulopenem in accordance with the Generating Antibiotics Incentives Now (GAIN) Act, which will provide five years of additional regulatory exclusivity and expedited Fast Track FDA review.

About Iterum Therapeutics plc

Iterum Therapeutics plc is a 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 Therapeutics is advancing its first compound, sulopenem, a novel penem anti-infective compound, in Phase 3 clinical development with oral and IV formulations. Sulopenem has demonstrated potent *in vitro* activity against a wide variety of gram-negative, gram-positive and anaerobic bacteria resistant to other antibiotics. Iterum Therapeutics has received Qualified Infectious Disease Product (QIDP) and Fast Track designations for its oral and IV formulations of sulopenem in seven indications. For more information, please visit http://www.iterumtx.com.

Forward-looking Statements

This press release may contain forward-looking statements. These forward-looking statements include, without limitation, statements regarding the development, therapeutic and market potential of sulopenem, and the timing, progress and results of clinical trials. In some cases, forward-looking statements can be identified by words such as “may,” “believes,” “intends,” “seeks,” “anticipates,” “plans,” “estimates,” “expects,” “should,” “assumes,” “continues,” “could,” “will,” “future,” “potential” or the negative of these or similar terms and phrases. Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Forward-looking statements include all matters that are not historical facts. Actual future results may be materially different from what is expected due to factors largely outside our control, including the uncertainties inherent in the conduct of clinical trials, availability and timing of data from clinical trials, changes in regulatory requirements or decisions of regulatory authorities, changes in public policy or legislation, the actions of third-party clinical research organizations, suppliers and manufacturers, commercialization plans and timelines, if approved, the accuracy of our expectations regarding how far into the future our cash on hand will fund our ongoing operations, the sufficiency of our cash resources and our ability to continue as a going concern, risks related to political, economic or business conditions, including risks related to health epidemics and other widespread outbreaks of contagious disease, including the novel coronavirus and other factors discussed under the caption “Risk Factors” in our Annual Report on Form 10-K filed with the Securities and Exchange Commission (the “SEC”), and other documents filed with the SEC from time to time. Forward-looking statements represent our beliefs and assumptions only as of the date of this press release. Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in the forward-looking statements, even if new information becomes available in the future.

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