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Iterum Therapeutics Announces Completion of Enrollment in Phase 3 Clinical Trial of Oral and IV Sulopenem in Complicated Urinary Tract Infection

Topline results expected in Q1 2020

DUBLIN, Ireland and CHICAGO, Nov. 18, 2019 (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 the completion of patient enrollment in its **Su**lopenem for **R**esistant **E**nterobacteriaceae (SURE) 2 clinical trial in complicated urinary tract infections (cUTI).

“The completion of enrollment in our cUTI trial marks the achievement of another critical milestone in our development program,” said Corey Fishman, Chief Executive Officer of Iterum Therapeutics. “Completing enrollment in this phase 3 trial brings us another step closer to providing physicians and patients with the first and only oral and intravenous (IV) penem antibiotic, if approved. We look forward to sharing topline results from the SURE 2 trial in early 2020.”

This multi-center, double-blind clinical trial is measuring efficacy, tolerability, and safety of IV and oral sulopenem for the treatment of cUTI in adults. Patients are randomized to receive either IV sulopenem once daily for a minimum of five days followed by oral sulopenem/probenecid twice daily to complete 7-10 days of treatment, or IV ertapenem once daily for a minimum of five days followed by oral ciprofloxacin twice daily or, for those patients with a baseline pathogen resistant to ciprofloxacin, to amoxicillin/clavulanate twice daily.

About Complicated Urinary Tract Infections

There are approximately 3.6 million patients with cUTIs that require antibiotic therapy every year in the United States. cUTIs, including acute pyelonephritis, are defined as urinary tract infections ascending from the bladder accompanied by local and systemic signs and symptoms, including fever, chills, malaise, flank pain, back pain, and/or costo-vertebral angle pain or tenderness, that occur in the presence of a functional or anatomical abnormality of the urinary tract or in the presence of catheterization, with treatment typically initiated by IV therapy in a hospital setting. The lack of effective oral step-down options for many patients with cUTIs has meant the potential for lengthy hospital stays or insertion of a peripherally inserted central catheter (PICC) to facilitate administration of IV antibiotics outside of the hospital.

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 of 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 and regulatory submissions. 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 Iterum Therapeutics’ 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 Iterum Therapeutics’ control, including the uncertainties inherent in the conduct of clinical trials, clinical trial patient enrollment, availability and timing of data from clinical trials, changes in regulatory requirements or decisions of regulatory authorities, including uncertainties associated with regulatory review of clinical trials and applications for marketing approval, changes in public policy or legislation, the actions of third-party clinical

research organizations, suppliers and manufacturers, commercialization plans and timelines, if approved, the sufficiency of our cash resources and other factors discussed under the caption “Risk Factors” in the Quarterly Report on Form 10-Q filed with the Securities and Exchange Commissions (SEC) on November 12, 2019, and other documents filed with the SEC from time to time. Forward-looking statements represent Iterum Therapeutics’ beliefs and assumptions only as of the date of this press release. Except as required by law, Iterum Therapeutics assumes 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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