August 9, 2018

Iterum Initiates SURE 1, a Phase 3 Clinical Trial of Oral Sulopenem in Uncomplicated Urinary Tract Infections

First of three planned Phase 3 pivotal trials now underway for Iterum's oral antibiotic

Oral sulopenem, if approved, could be the first antibiotic for uncomplicated urinary tract infections in over 20 years

Top-line results expected in 2H 2019 and NDA submission anticipated by the end of 2019

DUBLIN and CHICAGO, Aug. 09, 2018 (GLOBE NEWSWIRE) -- Iterum Therapeutics plc (Nasdaq: ITRM), a clinical-stage pharmaceutical company developing antibiotics against multi-drug resistant pathogens, today announced its initiation of the first of three Phase 3 clinical trials. In this trial, known as **Su**lopenem for **R**esistant **E**nterobacteriaceae (SURE) 1, oral sulopenem etzadroxil combined with probenecid in a bilayer tablet (oral sulopenem) is compared to oral ciprofloxacin in women with uncomplicated urinary tract infections (uUTI). Sulopenem is Iterum's lead compound and novel antibiotic for the treatment of gram-negative, multi-drug resistant infections.

"We are delighted to begin our first Phase 3 clinical trial for sulopenem early in the third quarter, consistent with our prior guidance. The commencement of our Phase 3 program marks an important milestone for our company," said Corey Fishman, Chief Executive Officer of Iterum. "We are leveraging our prior clinical trial data, and the important feedback we received from the FDA and European regulators, to conduct our Phase 3 trials, with data expected to readout in the second half of 2019. If approved, oral sulopenem would be the first new drug approved for uncomplicated UTIs in over 20 years and would provide a much-needed treatment option in a large and growing market."

"Multi-drug resistance in UTIs is alarmingly high and growing globally, and current treatment options are failing," said Michael Dunne, M.D., Chief Scientific Officer of Iterum. "In particular, resistance to fluoroquinolones continues to rise. Healthcare providers and their patients urgently need new oral options to effectively treat infections in the community such as UTIs. The U.S. Food and Drug Administration (FDA) has recently strengthened existing warnings for the fluoroquinolone class and maintains that healthcare professionals should not prescribe fluoroquinolones to patients who have other treatment options for uUTI as the risks outweigh the benefits."

The SURE 1 trial is a randomized, multi-center, double-blind study to measure efficacy, tolerability, and safety of oral sulopenem vs. oral ciprofloxacin for the treatment of uUTI in adult women. Patients will be randomized to receive either oral sulopenem twice daily for 5 days or oral ciprofloxacin twice daily for 3 days, the approved regimen in uUTI. The study is expected to enroll approximately 1,364 patients and will be conducted under a Special Protocol Assessment (SPA) agreement from the FDA. Iterum expects to announce top-line

results from this trial in the second half of 2019. For more information, please refer to www.clinicaltrials.gov using the identifier NCT03354598. The initiation of SURE 1 follows the successful completion of a Phase 1 study that documents the pharmacokinetics of the bilayer tablet which will be used in the clinical trial and is intended for commercial production.

Iterum is planning to initiate two additional Phase 3 clinical trials later this year that will utilize both oral and intravenous sulopenem in complicated urinary tract infections (cUTI) and complicated intra-abdominal infections (cIAI). The company expects to file its new drug applications (NDAs) with the FDA by the end of 2019 and has received QIDP designations for its oral and IV formulations for the treatment of uUTI, cUTI and cIAI.

About Urinary Tract Infections (UTIs)

UTIs are among the most common bacterial infections encountered in the community. There are approximately 13.5 million emergency room and office visits for symptoms of urinary tract infections and approximately 21 million uUTIs treated in the United States annually. The treatment of urinary tract infections has become more challenging because of the development of resistance by pathogens responsible for these diseases. uUTIs are infections of the bladder occurring mainly in women. Up to 10% of women have a urinary tract infection in a given year and 50% of all women experience at least one UTI at some point in their lives.

About Iterum Therapeutics plc

Iterum Therapeutics plc is a clinical-stage pharmaceutical company dedicated to developing differentiated antibiotics 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 antibiotic with oral and IV formulations that has demonstrated potent *in vitro* activity against a wide variety of gram-negative, gram-positive and anaerobic bacteria resistant to other antibiotics. For more information, please visit http://www.iterumtx.com.

Forward-looking Statements

This press release contains 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 the expected timing of NDA filings. 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 initiation and conduct of clinical trials, clinical trial patient enrolment, availability and timing of data from clinical trials, changes in regulatory requirements or decisions of regulatory authorities, commercialization plans and timelines, if approved, the actions of third-party clinical research organizations, suppliers and manufacturers and other factors discussed under the

caption “Risk Factors” in the final prospectus for Iterum Therapeutics’ initial public offering, which was filed with the Securities and Exchange Commission (the “SEC”) on May 25, 2018, 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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Source: Iterum Therapeutics plc