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# Iterum Therapeutics Announces Completion of Enrollment in Phase 3 Clinical Trial of Oral Sulopenem in Uncomplicated Urinary Tract Infection

## Topline results expected in Q1 2020

DUBLIN, Ireland and CHICAGO, Dec. 26, 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 **Sulopenem for Resistant Enterobacteriaceae (SURE)** 1 clinical trial in uncomplicated urinary tract infections (uUTI).

"We are pleased to announce the completion of enrollment in our final phase 3 trial for uncomplicated urinary tract infections (uUTI) with over 1,670 patients treated. Topline results from this trial are expected in the first quarter of 2020," said Corey Fishman, Chief Executive Officer of Iterum Therapeutics. "It has been over 20 years since a new, oral treatment has been developed for urinary tract infections and the existing orals are no longer effective. If approved, oral sulopenem will provide an option to those patients with an elevated risk for treatment failure that currently have no other alternatives."

This multi-center, double-blind clinical trial is measuring efficacy, tolerability, and safety of oral sulopenem/probenecid for the treatment of uUTI in adult women. Patients are randomized to receive either oral sulopenem/probenecid twice daily for 5 days of treatment, or oral ciprofloxacin twice daily for three days of treatment.

## About Uncomplicated Urinary Tract Infections

There are approximately 13.5 million emergency room and office visits for symptoms of UTIs and approximately 21 million uUTIs in the United States annually. Based on market research, physicians estimated that approximately 35% of these patients are at elevated risk for treatment failure. Proper antibiotic treatment of drug-resistant infections in this group is particularly important due to the consequences associated with treatment failure. Elevated risk patients were defined in the research as patients with recurrent UTIs, elderly patients, patients who have a suspected or confirmed drug-resistant infection, patients with comorbidities (e.g., Diabetes mellitus) or that are immunocompromised, patients that have had a recent hospitalization, patients with a history of prior antibiotic failure and patients in a long-term care setting.

## 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 Iterum Therapeutics’ cash resources and its ability to continue

as a going concern, and other factors discussed under the caption “Risk Factors” in Iterum Therapeutics’ most recently filed Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (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.

**Investor Contact:**

Judy Matthews  
Chief Financial Officer  
312-778-6073  
[IR@iterumtx.com](mailto:IR@iterumtx.com)

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