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Iterum Initiates SURE 2 and SURE 3 Phase 3 Clinical Trials of IV and Oral Sulopenem in Complicated Urinary Tract and Complicated Intra-abdominal Infections

Remaining two of three planned Phase 3 pivotal trials now underway for Iterum's lead antibiotic product candidate sulopenem

Potential to be first and only oral and IV penem antibiotic available globally

Top-line results for SURE 2 and SURE 3 expected in the second half of 2019, with new drug application (NDA) submissions anticipated by the end of 2019

DUBLIN, Ireland and CHICAGO, Sept. 18, 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 second and third of three planned Phase 3 clinical trials for sulopenem, Iterum's lead compound and novel antibiotic for the treatment of gram-negative, multi-drug resistant infections.

In the second trial, known as **Su**lopenem for **R**esistant **E**nterobacteriaceae (SURE) 2, IV sulopenem followed by oral sulopenem etzadroxil combined with probenecid in a bilayer tablet (oral sulopenem) will be compared to IV ertapenem followed by oral ciprofloxacin in adults with complicated urinary tract infections (cUTI). In the third trial, known as SURE 3, IV sulopenem followed by oral sulopenem is compared to IV ertapenem followed by a combination of oral ciprofloxacin and oral metronidazole in adults with complicated intra-abdominal infections (cIAI).

"We are excited to initiate SURE 2 and SURE 3, our remaining Phase 3 clinical trials for sulopenem, providing three indications at launch, if approved," said Corey Fishman, Chief Executive Officer of Iterum. "The initiation of these trials, together with SURE 1, which we initiated in early August, means that our entire Phase 3 clinical program for sulopenem is currently underway. Given this achievement, we reiterate our expectation of announcing top-line data from all three trials in the second half of 2019 and U.S. regulatory submissions by the end of 2019. We believe we are setting the stage for a series of value-creating, near-term milestones for Iterum that will be funded by our current cash resources."

"Multi-drug resistant cUTIs and cIAIs represent an important unmet medical need given the rising incidence of resistant infections and the paucity of new treatment options, particularly for oral step-down therapy," said Michael Dunne, M.D., Chief Scientific Officer of Iterum. "With slowing industry development of new classes of antibiotics, new treatment options are much needed as a solution to the rising rate of resistance to current antibiotics, particularly fluoroquinolones."

The SURE 2 trial is a randomized, multi-center, double-blind study to measure efficacy, tolerability, and safety of IV and oral sulopenem for the treatment of cUTI in adults. Patients will be randomized to receive either IV sulopenem once daily for a minimum of five days followed by oral sulopenem 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. The study is expected to enroll approximately 1,156 patients and will be conducted under a Special Protocol Assessment (SPA) agreement with the U.S. Food and Drug Administration (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 NCT03357614.

The SURE 3 trial is a randomized, multi-center, double-blind study to measure efficacy, tolerability, and safety of IV and oral sulopenem for the treatment of cIAI in adults. Patients will be randomized to receive either IV sulopenem once daily for a minimum of five days followed by oral sulopenem twice daily to complete 7-10 total days of treatment, or IV ertapenem once daily for a minimum of five days followed by oral ciprofloxacin twice daily along with oral metronidazole four times daily. The study is expected to enroll approximately 670 patients and will be conducted under a SPA agreement with 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 NCT03358576.

All three of Iterum's planned Phase 3 trials for sulopenem are now underway. The company expects to file its new drug applications for sulopenem with the FDA by the end of 2019 and has received qualified infectious disease product designations for its oral and IV formulations for the treatment of uUTI, cUTI and cIAI.

About Complicated Urinary Tract Infections and Complicated Intra-abdominal 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. For patients with cUTIs, the lack of effective oral step-down options and the paucity of new treatment options, which is demonstrated by the fact that none of the most commonly used oral agents were initially approved by the FDA in the last two decades, results in the potential for lengthy hospital stays or insertion of a PICC to facilitate administration of IV antibiotics, even for some patients with relatively straightforward infections.

cIAIs are the second most common cause of infectious mortality in intensive care units. These complicated infections extend from a gastrointestinal source, such as the appendix or the colon, into the peritoneal space and can be associated with abscess formation. Among approximately 350,000 cIAI patients in the United States each year, broad spectrum antibiotics are generally administered as first line treatment; treatment failure is more common due to the serious nature of these infections.

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 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, 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’s 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’s’ control, including the uncertainties inherent in the initiation and 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, 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 its Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (the “SEC”) on August 14, 2018, and other documents filed with the SEC from time to time. Forward-looking statements represent Iterum’s beliefs and assumptions only as of the date of this press release. Except as required by law, Iterum 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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