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Iterum Announces First Patient Dosed in REASSURE, a Phase 3 Clinical Trial of Oral Sulopenem in Uncomplicated Urinary Tract Infections

-- NDA resubmission expected in Second Half of 2024, if successful--

--Oral sulopenem, if approved, could be the first antibiotic approved for uncomplicated urinary tract infections in over 25 years--

DUBLIN, Ireland and CHICAGO, Oct. 20, 2022 (GLOBE NEWSWIRE) -- Iterum Therapeutics plc (Nasdaq: ITRM) (Iterum), a clinical-stage pharmaceutical company developing antibiotics to treat infections caused by multi-drug resistant pathogens, today announced that the first patient has been dosed in its Phase 3 clinical trial, known as **RE**newed **AS**sessment of **S**ulopenem in u**U**TI caused by **R**esistant **E**nterobacterales (REASSURE), comparing oral sulopenem (sulopenem etzadroxil combined with probenecid in a bilayer tablet) to oral Augmentin® (amoxicillin/clavulanate) in adult women with uncomplicated urinary tract infections (uUTI).

“We are pleased to have successfully dosed our first patient in our Phase 3 clinical trial for oral sulopenem for the treatment of uUTI, which is being conducted under a Special Protocol Assessment (SPA) agreement with the U.S. Food and Drug Administration (FDA),” said Corey Fishman, Chief Executive Officer. “We anticipate completing the trial in the first half of 2024 with our existing cash resources. With positive results, we would resubmit our new drug application (NDA) to the FDA in the second half of 2024.”

About REASSURE

The REASSURE trial is designed as a non-inferiority trial comparing oral sulopenem and Augmentin® in the Augmentin susceptible population and is entitled “A prospective, Phase 3, randomized, multi-center, double-blind study of the efficacy, tolerability, and safety of oral sulopenem etzadroxil/probenecid versus oral amoxicillin/clavulanate for treatment of uncomplicated urinary tract infections (uUTI) in adult women.” Patients will be randomized to receive either oral sulopenem twice daily for 5 days or Augmentin® twice daily for 5 days. The primary endpoint is the overall response (clinical and microbiologic combined response) at Day 12 of the trial. The trial is expected to enroll approximately 1,966 patients and is being conducted under a SPA agreement with the FDA.

Iterum expects to complete enrollment in the first half of 2024 and, if the Phase 3 clinical trial is successful, resubmit its NDA in the second half of 2024. If the resubmission addresses all deficiencies in the complete response letter received in July 2021 from the FDA, then the FDA’s review and action will occur six months from receipt of the resubmission.

For more information on REASSURE, please refer towww.clinicaltrials.gov using the identifier NCT05584657.

About Urinary Tract Infections (UTIs)

UTIs are among the most common bacterial infections encountered in the community. There are approximately 15 million emergency room and office visits for symptoms of urinary tract infections and approximately 33 million uUTIs treated in the United States annually, with approximately 30% of those infections caused by a quinolone non-susceptible organism, and approximately 1% of those infections caused by pathogens that are resistant to all commonly available classes of oral antibiotics. As a result, the treatment of UTIs has become more challenging because of the development of resistance by pathogens responsible for these infections. uUTIs are infections of the bladder occurring mainly in women. 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 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. Iterum has received Qualified Infectious Disease Product (QIDP) and Fast Track designations for its oral and IV formulations of sulopenem in seven indications including uUTI. 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, conduct, progress and results of Iterum's ongoing Phase 3 clinical trial, Iterum's expectations with regard to its ability to resolve matters set forth in the complete response letter (CRL) received by Iterum in July 2021 and obtain approval for oral sulopenem, the expected timing of resubmission of the NDA, and the sufficiency of Iterum's cash resources. 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," "would," "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 and non-clinical development, including the Phase 3 clinical trial and non-clinical development being conducted in response to the CRL, clinical trial patient enrolment, availability and timing of data from the Phase 3 clinical trial and non-clinical development, changes in regulatory requirements or decisions of regulatory authorities, the timing or likelihood of regulatory filing and approvals, including the potential resubmission of the NDA for oral sulopenem, changes

in public policy or legislation, commercialization plans and timelines, if oral sulopenem is approved, the actions of third-party clinical research organizations, suppliers and manufacturers, the accuracy of Iterum's expectations regarding how far into the future Iterum's cash on hand will fund Iterum's ongoing operations, the impact of COVID-19 and related responsive measures thereto, risks and uncertainties concerning the outcome, impact, effects and results of Iterum's evaluation of corporate, strategic, financial and financing alternatives, including the terms, timing, structure, value, benefits and costs of any corporate, strategic, financial or financial alternatives and Iterum's ability to complete one at all and other factors discussed under the caption "Risk Factors" in its Quarterly Report on Form 10-Q, which was filed with the Securities and Exchange Commission (SEC) on August 12, 2022, 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.

Contact:

Contact:
Judy Matthews
Chief Financial Officer
312-778-6073
IR@iterumtx.com

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