October 24, 2023

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

*– Topline Data Expected in Early Q1 2024–*

*– NDA Resubmission Expected in Q2 2024–*

DUBLIN, Ireland and CHICAGO, Oct. 24, 2023 (GLOBE NEWSWIRE) -- Iterum Therapeutics plc (Nasdaq: ITRM) (Iterum), 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 REASSURE (**RE**newed **AS**sessment of **S**ulopenem in u**U**TI caused by **R**esistant **E**nterobacterales) clinical trial 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 extremely pleased to have completed enrollment in our REASSURE trial well ahead of schedule. We now expect topline results early in the first quarter of 2024, and subject to our analysis of the data, plan to resubmit our NDA to the FDA in the second quarter of 2024,” said Corey Fishman, Chief Executive Officer. “This significant milestone represents another exciting step forward in the development of oral sulopenem and potentially bringing to market the first antibiotic approved for the treatment of uUTIs in over 25 years, as well as the first oral penem, in the U.S.”

Iterum expects to report topline data early in the first quarter of 2024 and, subject to its analysis of the data, to resubmit its New Drug Application (NDA) for oral sulopenem for the treatment of uUTIs to the U.S. Food and Drug Administration (FDA) in the second quarter of 2024. Provided that the resubmitted NDA addresses all of the deficiencies identified in the complete response letter Iterum received from the FDA in July 2021, Iterum expects that the FDA will complete its review and take action six months from the date the FDA receives the resubmitted NDA (or during 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 were 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 the test of cure visit. The trial enrolled approximately 2,230 patients and is being conducted under a special protocol assessment (SPA) agreement with the FDA.

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 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 is currently advancing its first compound, sulopenem, a novel penem anti-infective compound, in Phase 3 clinical development with an oral formulation. Sulopenem also has an IV formulation. Sulopenem 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.

**Special Note Regarding Forward Looking Statements**

This press release contains forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. These forward-looking statements include, without limitation, statements regarding the development, therapeutic and market potential of sulopenem, the timing and results of topline data from the REASSURE clinical trial, our ability to address the deficiencies set out in the complete response letter received in July 2021 and the expected timing of resubmission of the NDA. 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,” “would,” “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 uncertainties inherent in the conduct of

clinical and non-clinical development, including the REASSURE clinical trial, availability and timing of data from the REASSURE clinical trial, changes in regulatory requirements or decisions of regulatory authorities, the timing or likelihood of regulatory filings 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, Iterum's ability to maintain its listing on the Nasdaq Capital Market, 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 financing alternative 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 filed with the SEC on August 11, 2023, 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.

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

Source: Iterum Therapeutics PLC