September 10, 2024

Iterum Therapeutics Provides Update on FDA Advisory Committee Discussion of Oral Sulopenem for the Treatment of uUTI in Adult Women

FDA Decision Expected by PDUFA Goal Date of October 25, 2024

Potential to be First Oral Penem Approved in the U.S.

DUBLIN and CHICAGO, Sept. 10, 2024 (GLOBE NEWSWIRE) -- Iterum Therapeutics plc (Nasdaq: ITRM) (Iterum), a clinical-stage pharmaceutical company focused on developing next-generation oral antibiotics to treat infections caused by multi-drug resistant pathogens in community settings, today announced that a meeting of the U.S. Food and Drug Administration's (FDA) Antimicrobial Drugs Advisory Committee (AMDAC) took place on September 9, 2024 at which Iterum's new drug application (NDA) for sulopenem etzadroxil/probenecid (oral sulopenem) for the treatment of uncomplicated urinary tract infections (uUTI) in adult women was discussed.

Specifically, the FDA convened the AMDAC meeting to discuss a) the overall benefits and risks for the use of sulopenem etzadroxil/probenecid for the treatment of uUTI caused by designated susceptible microorganisms in adult women > 18 years of age, and b) considerations that would be important for medical providers to know to ensure appropriate use of sulopenem etzadroxil/probenecid. The FDA did not ask the AMDAC to vote on any matter.

"We are encouraged by the AMDAC's discussion which acknowledged oral sulopenem as an important treatment option for certain patients with uUTI and agree that the appropriate use of oral sulopenem by treating physicians is critical to limiting antimicrobial resistance," said Corey Fishman, Iterum's Chief Executive Officer. "We look forward to continuing to work with the FDA on the review of the NDA and potential labeling over the next few months."

The AMDAC was provided scientific evidence shared by Iterum, including data from the pivotal **REASSURE** (**RE**newed **AS**sessment of **S**ulopenem in u**U**TI caused by **R**esistant **E**nterobacterales) Phase 3 clinical trial, and data from the**SURE**-1 (**Su**lopenem for **R**esistant **E**nterobacteriaceae) Phase 3 clinical trial.

The FDA is not bound by the recommendations of the AMDAC but takes its advice into consideration. The FDA's decision on whether or not to approve oral sulopenem for the treatment of uUTIs in adult women is expected by the Prescription Drug User Fee Act (PDUFA) goal date of October 25, 2024.

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 UTIs and over 40 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. Half (50%) of all women experience at least one uUTI 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 Therapeutics is advancing the development of its first compound, sulopenem, a novel penem anti-infective compound, with an oral formulation and 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 Therapeutics has submitted an NDA for oral sulopenem for the treatment of uncomplicated urinary tract infections in adult women, which has been accepted for review by the U.S. Food and Drug Administration and 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 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 date by which the FDA will take action regarding Iterum's NDA for oral sulopenem and Iterum's plans, strategies and prospects for its business, including the development, therapeutic and market potential of sulopenem. 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 design, initiation and conduct of clinical and non-clinical development, changes in regulatory requirements or decisions of regulatory authorities, the timing or likelihood of regulatory filings and approvals, 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 sufficiency of Iterum's cash resources and Iterum's ability to continue as a going concern, Iterum's ability to regain and maintain its listing on the

Nasdaq Capital Market, risks and uncertainties concerning the outcome, impact, effects and results of Iterum's pursuit of strategic alternatives, including the terms, timing, structure, value, benefits and costs of any strategic process and Iterum's ability to complete one, whether on attractive terms or at all, and other factors discussed under the caption "Risk Factors" in its Annual Report on Form 10-Q filed with the SEC on August 14, 2024, 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

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