April 29, 2024

Iterum Therapeutics Resubmits New Drug Application to U.S. Food and Drug Administration for Oral Sulopenem

--First Oral Penem in the U.S. and Second New Oral Treatment for uUTIs in Over 25 Years, if approved--

--Potential Approval Early Q4 2024--

DUBLIN, Ireland and CHICAGO, April 29, 2024 (GLOBE NEWSWIRE) -- Iterum Therapeutics plc (Nasdaq: ITRM) (the Company), 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 that it has resubmitted its New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for sulopenem etzadroxil/probenecid (oral sulopenem) for the treatment of uncomplicated urinary tract infections (uUTIs) in adult women.

“The resubmission of the NDA filing for oral sulopenem is a significant step forward in bringing a new antibiotic to the market for women that suffer from an estimated 40 million uUTIs each year in the U.S.,” said Corey Fishman, Chief Executive Officer. “The availability of oral sulopenem, if approved, would mean that physicians and patients have the opportunity to benefit from the proven efficacy and safety of penem antibiotics that, to date in the U.S., have only been available in IV formulations. We look forward to working with the FDA through the review process to advance this much needed treatment option."

The NDA resubmission includes data from the REASSURE (**RE**newed **AS**sessment of **S**ulopenem in u**U**TI caused by **R**esistant **E**nterobacterales), SURE (**Su**lopenem for **R**esistant **E**nterobacteriaceae) 1, SURE 2 and SURE 3 phase 3 clinical trials, in which oral sulopenem was well tolerated with no safety issues identified. The REASSURE clinical trial comparing oral sulopenem to oral Augmentin® in adult women with a uUTI, demonstrated that oral sulopenem was non-inferior to Augmentin® for the primary efficacy endpoint of clinical and microbiologic response at the test-of-cure visit for patients with an Augmentin® susceptible pathogen, with the difference in the overall success rate demonstrating statistically significant superiority of oral sulopenem versus Augmentin®. The SURE 1 clinical trial comparing oral sulopenem to oral ciprofloxacin in adult women with a uUTI, demonstrated statistical superiority of oral sulopenem to the widely used comparator, ciprofloxacin, for the primary efficacy endpoint of clinical and microbiologic response at the test-of-cure visit for patients with a quinolone non-susceptible pathogen.

Provided that the resubmitted NDA addresses all of the deficiencies identified in the complete response letter (CRL) the Company received from the FDA in July 2021, the Company expects that the FDA will complete its review and take action six months from the date the FDA received the resubmitted NDA (or early in the fourth quarter of 2024).

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. The Company is advancing its first compound, sulopenem, a novel penem anti-infective compound, in Phase 3 clinical development 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. The Company has received Qualified Infectious Disease Product (QIDP) and Fast Track designations for its oral and IV formulations of sulopenem in seven indications.

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 Company's plans, strategies and prospects for its business, including the development, therapeutic and market potential of sulopenem, the Company's ability to address the deficiencies set out in the CRL received in July 2021, and the expected timing of review of the NDA by the FDA. 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 the Company'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 the Company's control, including the uncertainties inherent in the initiation and conduct of clinical and non-clinical development, changes in regulatory requirements or decisions of regulatory authorities, the timing of approval of any submission, 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 the Company's expectations regarding how far into the future the Company's cash on hand will fund the Company's ongoing operations, the sufficiency of the Company's cash resources and the Company's ability to continue as a going concern, the Company's ability to maintain listing on the Nasdaq Capital Market, risks and uncertainties concerning the outcome, impact, effects and results of the Company's pursuit of strategic alternatives, including the terms, timing, structure, value, benefits and costs of any strategic process and the Company's ability to complete one, whether on attractive terms or at all, and other factors discussed under the caption "Risk Factors" in its most recently filed Annual Report on Form 10-K filed with the US Securities and Exchange Commission (SEC) on March 28, 2024, and other documents filed with the SEC from time to time. Forward-looking statements represent the Company's beliefs and assumptions only as of the date of this press release. Except as required by law, the Company 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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