January 25, 2021

Iterum Therapeutics Announces U.S. FDA Filing Acceptance of New Drug Application for Oral Sulopenem

-- If approved, First Oral Penem in the U.S. and First New Oral Treatment for uUTIs in Over 20 Years --

-- PDUFA goal date of July 25, 2021 --

DUBLIN, Ireland and CHICAGO, Jan. 25, 2021 (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 the U.S. Food and Drug Administration (FDA) accepted for review the New Drug Application (NDA) for sulopenem etzadroxil/probenecid (oral sulopenem) for the treatment of uncomplicated urinary tract infections (uUTIs) in patients with a quinolone non-susceptible pathogen. The FDA has designated this application as a priority review and consequently assigned a PDUFA (Prescription Drug User Fee Act) goal date for completion of the review of oral sulopenem of July 25, 2021. The agency currently plans to hold an advisory committee meeting to discuss the NDA.

“The FDA acceptance of our NDA for review is an important milestone for Iterum. If approved, oral sulopenem would be the first penem available orally in the U.S. with the ability to treat multi-drug resistant infections in the community,” said Corey Fishman, Chief Executive Officer. “Specifically, this important antibiotic is one step closer to relieving the growing problem of quinolone resistance found in over six million uncomplicated urinary tract infections in the U.S. each year."

The NDA includes data from the SURE-1, SURE-2 and SURE-3 phase 3 clinical trials, in which oral sulopenem was well tolerated. The SURE-1 clinical trial (uUTIs) 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.

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 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. Iterum Therapeutics 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. These forward-looking statements include, without limitation, statements regarding, among other things, timing of the review of regulatory filings and the market opportunity for, and potential market acceptance of, oral sulopenem for uUTIs, and the Company's plans, strategies and prospects for its business. 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 trials, availability and timing of data from clinical trials, 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 impact of COVID-19 and related responsive measures thereto, 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 evaluation of corporate, organizational, strategic, financial and financing alternatives, including the terms, timing, structure, value, benefits and costs of any corporate, organizational, strategic, financial or financing alternative and the Company's ability to complete one at all, the price of the Company's securities and other factors discussed under the caption "Risk Factors" in its most recently filed Quarterly Report on Form 10-Q, 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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Source: Iterum Therapeutics plc