September 30, 2020

Iterum Therapeutics Announces Positive Pre-NDA Meeting with FDA for Sulopenem for Treatment of Uncomplicated Urinary Tract Infections

--Preparing to Submit NDA in Q4--

DUBLIN, Ireland and CHICAGO, Sept. 30, 2020 (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, based on discussions at a pre-NDA meeting with the U.S. Food and Drug Administration ("FDA"), it plans to proceed with an NDA submission for sulopenem etzadroxil/probenecid, a bilayer tablet, for the treatment of uncomplicated urinary tract infections (uUTI) in patients with a quinolone-resistant pathogen.

“We are pleased with the collaborative tone of our meeting with the FDA, and we believe that we now have a solid understanding of the Agency's requirements for our submission and the focus of their review,” said Corey Fishman, Chief Executive Officer. “Based on feedback received during this meeting and from previous correspondence, we have confidence in our decision to move forward with our NDA package for sulopenem etzadroxil/probenecid for the treatment of uUTI due to quinolone-resistant pathogens. We estimate that there are over 6 million quinolone-resistant urinary tract infections annually in the U.S., many of which are also multi-drug resistant, and sulopenem has demonstrated superiority versus ciprofloxacin in treating these infections.”

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, the Company’s plans

to move forward with its NDA package for sulopenem etzadroxil/probenecid, the timing of preparation of such NDA submission, the FDA requirements for such NDA submission 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 Company's ability to apply for regulatory approval and the timing of approval of any submission, changes in public policy or legislation, commercialization plans and timelines, if 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 Stock 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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