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Iterum Therapeutics Provides Update from FDA Type A Meeting Regarding Oral Sulopenem

DUBLIN, Ireland and CHICAGO, Sept. 28, 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 Company held a Type A meeting with the U.S. Food and Drug Administration (FDA) during the third quarter of 2021 to discuss the steps required for potential resubmission of the New Drug Application (NDA) for sulopenem etzadroxil/probenecid (oral sulopenem) for the treatment of uncomplicated urinary tract infections (uUTI).

In July, the Company announced that it had received a Complete Response Letter (CRL) from the FDA requesting additional data to support approval of oral sulopenem for the treatment of adult women with a uUTI.

“We had a successful meeting with the FDA and have established various potential paths forward to address the request in the CRL for additional data in support of our NDA,” said Corey Fishman, Chief Executive Officer. “We are currently evaluating the optimal design for an additional Phase 3 uUTI study to be conducted prior to the potential resubmission of the NDA. We continue to believe in the ability of sulopenem to treat the growing problem of multi-drug resistant UTIs in the community.”

Iterum notes that cash, cash equivalents and short-term investments were $91.5 million at the end of the second quarter of 2021. Based on the current operating plan and subject to final determination of the design and planned conduct of additional clinical and potential nonclinical development for sulopenem, the Company believes that it is well positioned financially to fund its operations into the second half of 2023.

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 the Company's plans, strategies and prospects for its business, including with respect to planned interactions and communications with the FDA and the ability to reach agreement with the FDA on the design of any potential future clinical trials, the Company's expectations with regard to its ability to resolve the matters set forth in the CRL and obtain approval for oral sulopenem, the conduct of potential future clinical and nonclinical development of sulopenem and the sufficiency of the Company's cash resources. 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 uncertainties inherent in the initiation and conduct of clinical and nonclinical development, including any additional trials that may be conducted in response to the CRL, availability and timing of data from such clinical and nonclinical development, changes in regulatory requirements or decisions of regulatory authorities, the timing or likelihood of regulatory filings and approvals, including any potential resubmission of the NDA, 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 impact of COVID-19 and related responsive measures thereto, risks and uncertainties concerning the outcome, impact, effects and results of the Company'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 the Company'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 Securities and Exchange Commission (the "SEC") on August 13, 2021, 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.

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

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