May 11, 2022

Iterum Therapeutics Provides Regulatory Update

DUBLIN, Ireland and CHICAGO, May 11, 2022 (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 it met with the US Food and Drug Administration (“FDA”) on May 5, 2022, to discuss its proposed plan to conduct one additional Phase 3 clinical trial to support the potential resubmission of the Company’s new drug application (“NDA") for oral sulopenem etzadroxil-probenecid (“oral sulopenem”) for the treatment of uncomplicated urinary tract infections (“uUTI”).

“We are pleased to announce that we have reached general alignment with the FDA on key aspects of our proposed trial design to support the potential resubmission of the NDA for uUTI,” said Corey Fishman, Chief Executive Officer. “We are designing this additional Phase 3 clinical trial as a non-inferiority trial comparing oral sulopenem and Augmentin® (amoxicillin/clavulanate) for the treatment of uUTI in adult women. We intend to request an agreement with the FDA regarding the proposed protocol under the special protocol assessment (“SPA”) process in the coming weeks and subject to finalization and receipt of the SPA agreement, we plan to initiate enrollment in the second half of 2022.”

A SPA agreement reflects the FDA’s concurrence with critical design elements in a protocol but does not guarantee that the FDA will file or approve an application that is supported by a clinical trial that is conducted in accordance with such protocol received from a sponsor.

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 Iterum’s plans, strategies and prospects for its business, including with respect to planned interactions with the FDA and Iterum’s ability

to finalize a SPA agreement with the FDA, Iterum's expectations with regard to its ability to resolve the matters set forth in the complete response letter (CRL) received by Iterum in July 2021 and obtain approval for oral sulopenem, and the design, timing and conduct of future clinical and non-clinical development of sulopenem to support a potential resubmission of the NDA for oral 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, including any additional clinical trials and non-clinical development conducted in response to the CRL, availability and timing of data from such potential clinical and non-clinical 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 for oral sulopenem, 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 including completing potential additional clinical and non-clinical development of oral sulopenem, the impact of COVID-19 and related responsive measures thereto, Iterum's ability to maintain its listing on the Nasdaq Stock Market, risks and uncertainties concerning the outcome, impact, effects and results of Iterum'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 Iterum's ability to complete one at all and other factors discussed under the caption "Risk Factors" in its Annual Report on Form 10-K filed with the Securities and Exchange Commission (the "SEC") on March 28, 2022, 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.

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Source: Iterum Therapeutics plc