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Iterum Therapeutics announces Issuance of Allowance for a U.S. Patent Covering Oral Sulopenem

DUBLIN, Ireland and CHICAGO, Sept. 19, 2022 (GLOBE NEWSWIRE) -- Iterum Therapeutics plc (Nasdaq: ITRM) (the "Company" or "Iterum"), 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 the United States Patent and Trademark Office has issued the Company a Notice of Allowance for U.S. patent application number 16/972,300 entitled "Combinations of Beta-Lactam Compounds and Probenecid and Uses Thereof" directed to the composition of the bilayer tablet of sulopenem etzadroxil and probenecid ("oral sulopenem") and its related uses.

"This patent allowance provides up to 10 years additional patent protection for our lead candidate and is a significant milestone for Iterum in protecting the long-term commercial potential of oral sulopenem, which, if approved, would be the first penem available orally in the U.S. as well as the first new oral treatment for uncomplicated urinary tract infections in over 20 years," said Corey Fishman, Chief Executive Officer. "We remain focused on preparing for our planned pivotal Phase 3 clinical trial for oral sulopenem for the treatment of uncomplicated urinary tract infections, and look forward to commencing enrollment in the coming weeks."

This Notice of Allowance concludes the substantive examination of the patent application and will result in the issuance of a U.S. patent after administrative processes are completed. The U.S. patent scheduled to issue from this application will expire no earlier than 2039, absent any extensions. Existing patent protection for sulopenem etzadroxil is scheduled to expire in 2029, subject to potential extension.

The Company's patent portfolio also contains pending patent applications outside the U.S. including Europe and China, submitted following receipt of the Written Opinion of the International Search Authority indicating that several claims directed to the composition of the bilayer tablet of oral sulopenem are novel and inventive.

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 potential approval of oral sulopenem by the U.S. Food and Drug Administration (the "FDA"), the timing and conduct of a planned Phase 3 clinical trial for oral sulopenem and the expected issuance of a U.S. patent in connection with the notice of allowance described above, including the timing thereof, and the protection provided by such patent. 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 design, initiation and conduct of clinical and non-clinical development, including the planned clinical trial and non-clinical development to be conducted in response to the complete response letter received from the FDA in July 2021, availability and timing of data from the planned clinical and non-clinical development, changes in regulatory requirements or decisions of regulatory authorities, the timing or likelihood of regulatory filings and approvals, including the potential resubmission of the new drug application to the FDA 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, the impact of COVID-19 and related responsive measures thereto, 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 Quarterly Report on Form 10- Q filed with the Securities and Exchange Commission (the "SEC") on August 12, 2022, 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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