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Iterum Therapeutics Broadens Patent Estate for Oral Sulopenem

DUBLIN and CHICAGO, Aug. 02, 2024 (GLOBE NEWSWIRE) -- Iterum Therapeutics plc (Nasdaq: ITRM) (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 (USPTO) has issued a notice allowance for two U.S. patents and the Canadian Intellectual Property Office (CIPO) has issued a Canadian patent, all related to sulopenem etzadroxil and probenecid (oral sulopenem).

"We are very pleased to continue to strengthen our oral sulopenem patent estate further with the addition of these new patents and extending existing protection to cover Canada," said Corey Fishman, Chief Executive Officer.

The USPTO has issued Iterum a Notice of Allowance for U.S. patent application number 18/065,400 entitled "Combinations of Beta-Lactam Compounds and Probenecid and Uses Thereof" that covers the use of Iterum's candidate combination of sulopenem etzadroxil and probenecid in treating uncomplicated urinary tract infection. 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 April 1, 2039, absent any extensions.

The USPTO has also issued Iterum a Notice of Allowance for U.S. patent application number 17/198,335 entitled "Combinations of Beta-Lactam Compounds, Probenecid, and Valproic Acid and Uses Thereof" that covers the use of sulopenem etzadroxil, probenecid, and valproic acid in treating specified infections. 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 March 11, 2041, absent any extensions.

The CIPO issued Iterum a Notice of Allowance for Canadian patent application number 3129337 entitled "Combinations of Beta-Lactam Compounds and Probenecid and Uses Thereof" that covers a bilayer tablet comprising sulopenem etzadroxil and probenecid, methods of preparing the bilayer tablet, and the use of the bilayer tablet in treating specified diseases. This Notice of Allowance concludes the substantive examination of the patent application and will result in the issuance of a Canadian patent after administrative processes are completed. The Canadian patent scheduled to issue from this application will expire December 23, 2039, absent any extensions.

Iterum's patent portfolio also contains pending patent applications in a number of other jurisdictions 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 the development of its first compound, sulopenem, a novel penem anti-infective compound, 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 submitted an NDA for oral sulopenem for the treatment of uncomplicated urinary tract infections in adult women, which has been accepted for review by the U.S. Food and Drug Administration and 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 within the meaning of The Private Securities Litigation Reform Act of 1995. These forward-looking statements include, without limitation, statements regarding the expected issuance of two U.S. patents and a Canadian patent in connection with the notices of allowance described above. 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, changes in regulatory requirements or decisions of regulatory authorities, the timing or likelihood of regulatory filings and approvals, 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 sufficiency of Iterum’s cash resources and Iterum’s ability to continue as a going concern, Iterum’s ability to regain and maintain its listing on the Nasdaq Capital Market, risks and uncertainties concerning the outcome, impact, effects and results of Iterum’s pursuit of strategic alternatives, including the terms, timing, structure, value, benefits and costs of any strategic process and Iterum’s ability to complete one, whether on attractive terms or at all, and other factors discussed under the caption “Risk Factors” in its Annual Report on Form 10-Q filed with the SEC on March 31, 2024, 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.

Investor Contact:

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



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