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Iterum Therapeutics Announces Filing of US Patent Application Based on Favorable Written Opinion of the International Search Authority

Bilayer tablet patent application could provide U.S. patent coverage for Iterum's commercial formulation through 2039, if granted

DUBLIN, Ireland and CHICAGO, Dec. 07, 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 the filing of a U.S. national phase patent application directed to the composition of the bilayer tablet of sulopenem etzadroxil and probenecid and its related uses with the U.S. Patent and Trademark Office ("USPTO").

"If approved, this U.S. patent application related to the bilayer tablet, which includes both sulopenem etzadroxil as well as probenecid, could provide U.S. patent coverage for Iterum's commercial formulation out to 2039, excluding any additional term for patent term adjustment or patent term extension, thereby extending the current patent protection afforded by the existing sulopenem etzadroxil patent estate," said Corey Fishman, Chief Executive Officer. "We are encouraged by the Written Opinion of the International Search Authority, which indicates that several claims directed to the composition of the tablet are novel and inventive. We anticipate additional patent filings in countries outside the U.S., including Europe and China, which should help facilitate partnering discussions in those regions."

The sulopenem bilayer tablet contains sulopenem etzadroxil, a prodrug of sulopenem that enables oral bioavailability, and probenecid, a renal tubular transport blocking agent, which together enhance the exposure of sulopenem to the bacterial pathogen responsible for the infection. These claims encompass the oral formulation used in the Phase 3 registration studies to support the safety and efficacy of sulopenem etzadroxil and probenecid. An extension of the life of the patent estate would enable pursuit of claims related to our previously granted QIDP indications such as pneumonia.

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. The licensed U.S. patent claim for a composition of matter patent for sulopenem etzadroxil is due to expire in 2029, subject to potential extension of up to 2034 under the Drug Price Competition and Patent Term Restoration Act of 1984 (referred to as the Hatch-Waxman Act).

Forward-Looking Statements

This press release contains forward-looking statements. These forward-looking statements include, without limitation, statements regarding the Company's ability to obtain patent protection for oral sulopenem, 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 timing of approval of any submission, 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, risks regarding intellectual property rights in product candidates and the ability to defend and enforce any such intellectual property rights, 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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