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Iterum Therapeutics Announces Extension of Term of Promissory Note

DUBLIN and CHICAGO, May 19, 2025 (GLOBE NEWSWIRE) -- Iterum Therapeutics plc (Nasdaq: ITRM) (the “Company” or “Iterum”), a company focused on delivering next generation oral and IV antibiotics to treat infections caused by multi-drug resistant pathogens in both community and hospital settings, today reported that Pfizer Inc. (“Pfizer”) has agreed to extend the term for payment of the regulatory milestone payment of $20.0 million until October 25, 2029.

“We are very pleased to announce that Pfizer has agreed to extend the due date for payment of the regulatory milestone associated with ORLYNVAH™’s approval by the FDA,” said Corey Fishman, Iterum’s Chief Executive Officer. “The $20.0 million promissory note was due October 2026 and is now due October 2029. As a result, any capital raised or earned in the near term from the sales of ORLYNVAH™ can be strategically invested to enable a successful launch of ORLYNVAH™, including through the expansion into new territories or concentration of resources in high prescribing geographies.”

Pursuant to the license agreement entered into on November 18, 2015, by and among the Company, Iterum Therapeutics International Limited (“ITIL”) and Pfizer (the “Pfizer License Agreement”), ITIL agreed to make a regulatory milestone payment of $20.0 million to Pfizer (the “Milestone Payment”) upon the approval of oral sulopenem for commercial sale in the United States by the U.S. Food and Drug Administration (“FDA”). The Company had the option to deliver notice of its election to defer such payment for up to two years from the date of approval and have a promissory note issued by ITIL in the amount of the Milestone Payment to Pfizer. After receiving FDA approval for ORLYNVAH™ on October, 25, 2024, the Company notified Pfizer on October 28, 2024, that it was electing to defer payment of the Milestone Payment for two years, or until October 25, 2026 (the “Deferral Period”), and a promissory note was issued to Pfizer by ITIL.

On May 13, 2025, the Company and ITIL entered into an amended and restated promissory note (the “A&R Note”) and a letter agreement relating to the A&R Note and amending the Pfizer License Agreement. The A&R Note extends the Deferral Period by an additional three years, or until October 25, 2029. In connection with the extension, ITIL agreed in the A&R Note to increase the annual rate of interest from eight percent (8%) to ten percent (10%) on a daily compounded basis, beginning on October 26, 2026. ITIL also agreed that it would not, directly or indirectly, (1) create, incur, assume, guaranty or otherwise become liable for any indebtedness that is senior in right of payment to the A&R Note, except for indebtedness incurred with the consent or waiver of Pfizer, or (2) create, grant or incur any lien on any of its property or assets, subject to specified exceptions (including liens securing permitted indebtedness and liens incurred with the consent or waiver of Pfizer). ITIL also agreed to pay Pfizer a transaction fee and to pay Pfizer’s legal expenses.

About Iterum Therapeutics plc

Iterum is focused on delivering 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 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 has received approval of its NDA for ORLYNVAH™ (oral sulopenem) for the treatment of uncomplicated urinary tract infections caused by the designated microorganisms *Escherichia coli*, *Klebsiella pneumoniae*, or *Proteus mirabilis* in adult women with limited or no alternative oral antibacterial treatment options by the FDA and has received Qualified Infectious Disease Product (QIDP) and Fast Track designations for its oral and IV formulations of sulopenem in seven indications. For more information, please visit www.iterumtx.com.

About ORLYNVAH™

ORLYNVAH™ is a novel oral penem antibiotic for the treatment of uUTIs. ORLYNVAH™ possesses potent activity against species of Enterobacterales including those that encode extended spectrum beta-lactamase (ESBL) or AmpC-type beta-lactamases that confer resistance to third generation cephalosporins.

Cautionary Note Regarding 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 Iterum's plans, strategies and prospects for its business, including the development, therapeutic and market potential of ORLYNVAH™, Iterum's ability to complete pre-commercialization activities for ORLYNVAH™ and Iterum's ability to prepare and implement commercialization plans for ORLYNVAH™, including Iterum's ability to expand into new territories and put additional resources in high prescribing geographies. 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 risks and uncertainties concerning the outcome, impact, effects and results of Iterum's evaluation of strategic alternatives, including the terms, timing, structure, value, benefits and costs of any strategic alternatives, Iterum's ability to complete a strategic alternative transaction, Iterum's ability to raise sufficient capital and successfully prepare and implement commercialization plans for ORLYNVAH™ with a commercial partner or directly, including Iterum's ability to build and maintain a sales force and prepare for a potential commercial launch of ORLYNVAH™, the ability of shareholders and other stakeholders to realize any value or recovery as part of a wind down process if Iterum is unsuccessful at entering into or completing a strategic transaction or preparing and implementing commercialization plans for ORLYNVAH™, the market opportunity for and the potential

market acceptance of ORLYNVAH™ for uUTIs caused by certain designated microorganisms in adult women who have limited or no alternative oral antibacterial treatment options, Iterum's ability to continue as a going concern, uncertainties inherent in the 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, 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, Iterum's ability to maintain its listing on the Nasdaq Capital Market and other factors discussed under the caption "Risk Factors" in its Quarterly Report on Form 10-Q filed with the SEC on May 13, 2025, and other documents filed with the Securities and Exchange Commission 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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