February 13, 2026

Iterum Therapeutics Provides Business Update

--Expanded Market Access and Patent Protection for ORLYNVAH™

--FDA correspondence regarding the use of ORLYNVAH™ as step-down therapy

DUBLIN and CHICAGO, Feb. 13, 2026 (GLOBE NEWSWIRE) -- Iterum Therapeutics plc (Nasdaq: ITRM) (the “Company” or “Iterum” or “we”), 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 provided a business update.

Recent Events

- **Market Access Update**:
  - **Medicare Part D Milestone**: We are pleased to announce another signed rebate agreement with one of the top three Medicare Part D Pharmacy Benefit Managers, in addition to our existing agreements with the other two of the top three. This agreement positions ORLYNVAH™ for inclusion on their Medicare Advantage Prescription Drug and Medicare Prescription Drug formularies, with coverage of more than 3.5 million lives expected to begin as early as this quarter.
- **Patent Portfolio:** Iterum has been granted a patent in the United States as patent number 12,544,337, entitled “Combinations of Beta-Lactam Compounds and Probenecid and Uses Thereof”, that covers a bilayer tablet comprising sulopenem etzadroxil and probenecid, a method of making the bilayer tablet, and methods of treating diseases, including uncomplicated urinary tract infection. This US patent is projected to expire in December 2039, absent any patent term extensions, and assuming timely payments of all maintenance fees during the lifetime of the patent. This patent is Orange Book listable, and if added, will total five U.S. patents listed in the FDA’s Orange Book.
- **FDA:** The US Food and Drug Administration (“FDA”) has responded to Iterum’s request to discuss the use of ORLYNVAH™ as step-down therapy and the collection of real world data to support the proposed claim. The FDA has determined that Iterum would need to provide substantial evidence of effectiveness from an adequate and well-designed clinical trial in a supplemental new drug application (sNDA) to support the proposed indication for ORLYNVAH™ as step-down treatment of complicated urinary tract infections (cUTI). The FDA recommends that Iterum request a Type C meeting to discuss the design and endpoints of any proposed clinical investigation to support the proposed indication.

About Iterum Therapeutics plc

Iterum Therapeutics plc 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 New Drug Application (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™ (oral sulopenem) is a novel oral penem antibiotic for the treatment of uUTIs. ORLYNVAH™ possesses potent activity against species of Enterobacterales including those that encode ESBL or AmpC-type ß-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 and the development, therapeutic and market potential of ORLYNVAH™. 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 Iterum's ability to raise sufficient capital and successfully implement its commercialization plans for ORLYNVAH™ with its commercial sales organization partners, Iterum's ability to expand and maintain a sales force, the protection provided by Iterum's patents, 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 implementing its commercialization of 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, uptake of ORLYNVAH™ by physicians and payer coverage, existing or new competition for ORLYNVAH™, 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 November 14, 2025, 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

Source: Iterum Therapeutics PLC