November 24, 2025

Iterum Therapeutics Provides Business Update

DUBLIN, Ireland and CHICAGO, Nov. 24, 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 provided a business update.

Recent Events

- **Specialty Distributor Now Stocked**: ORLYNVAH™ is now available at McKesson, which will allow certain physicians the ability to procure the product directly from McKesson through this specialty distribution channel, consistent with their practice preferences.

- **Sulopenem Susceptibility Disc FDA Cleared & Now Available to Order**: Iterum has received 510(k) clearance by the U.S. Food and Drug Administration (FDA) of its 2 µg Antimicrobial Susceptibility Test Disc. This disc, manufactured by Liofilchem®, is intended for use in microbiology laboratories for susceptibility testing by the disc diffusion method to determine susceptibility of Enterobacterales to sulopenem, utilizing FDA Susceptibility Test Interpretive Criteria. Antimicrobial susceptibility testing helps guide clinicians to use effective and targeted therapies for individual patients and is a key component of antimicrobial stewardship, helping to combat the growing threat of antimicrobial resistance. Liofilchem® has received authorization from FDA’s Global Unique Device Identification Database for the commercialization of the sulopenem susceptibility disc in the United States. For Microbiology Laboratories and Antimicrobial Stewardship Committees who are interested in sulopenem susceptibility testing, discs are now available and can be ordered at Liofilchem, Inc. (Waltham, MA) either by phone (781-902-0312) or by email (orders@liofilchem.us).

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, including the ability of physicians to procure ORLYNVAH™ via the McKesson speciality distribution channel 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 partner, EVERSANA, including 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.

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