September 19, 2025

Iterum Therapeutics Provides Business Update

DUBLIN and CHICAGO, Sept. 19, 2025 (GLOBE NEWSWIRE) -- Iterum Therapeutics plc (Nasdaq: ITRM) (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 general business update.

- **ORLYNVAH™ Launch Update**
  - In partnership with EVERSANA Life Science Services, LLC ("EVERSANA"), ORLYNVAH™ was launched in August 2025 into the community market in the U.S. in targeted territories across seven states.
  - Sales representatives, contracted by and dedicated to Iterum via EVERSANA, have been actively engaging with target physicians who have shown interest in learning more about ORLYNVAH™ and recommended patient profiles; these discussions have begun to result in prescriptions being written for ORLYNVAH™.
  - Iterum has received inbound inquiries from non-target physicians to learn more about ORLYNVAH™ and potential to gain access to the product.
  - Market Access
    - National Account Managers continue to actively engage with key stakeholders across the U.S. payer landscape and have been presenting ORLYNVAH™'s differentiated value proposition and advancing formulary coverage discussions with state, regional, and national health plans, including the three largest pharmacy benefit managers (PBMs) serving the health plans.
    - ORLYNVAH™ remains broadly accessible via prior authorization and medical exception pathways, consistent with standard "new-to-market" coverage protocols. While formal committee reviews and rebate contracting negotiations are ongoing, Iterum is committed to maintaining momentum to secure expanded access and long-term formulary positioning, which Iterum aims to achieve later this year and through the first quarter of 2026.
  - Iterum has received 510(k) clearance by the U.S. Food and Drug Administration of its 2 µg Antimicrobial Susceptibility Test Disc which will allow the device to be marketed and used in microbiology labs for susceptibility testing by the disc diffusion method. Antimicrobial susceptibility testing helps guide clinicians to use effective and targeted therapy for individual patients and is a key component of antimicrobial stewardship, helping to combat the growing threat of antimicrobial resistance.

- **Cash Runway**
  - Based on Iterum's current operating plan, Iterum expects that its cash and cash equivalents as of June 30, 2025, together with $2.2 million of net proceeds raised under its at-the-market offering program from July 1, 2025 through August 1,

2025, will be sufficient to fund its operations into 2026. Iterum will continue to explore all available financing opportunities, including non-dilutive funding, to extend its operating runway.

- **Patent Estate Updates**
  - Iterum has been granted a patent in China as patent number ZL202180020106.6, entitled "*Combinations of Beta-Lactam Compounds, Probenecid, and Valproic Acid and Uses Thereof*", that covers a combination of sulopenem etzadroxil, probenecid, and valproic acid for treating specified diseases. This Chinese patent is projected to expire in March 2041, absent any patent term extensions, and assuming timely payments of all maintenance fees during the lifetime of the patent.
  - Iterum has been granted a patent in Mexico as patent number 426995, 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 bilayer tablet for use in treating specified diseases. This Mexican 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.
  - Iterum continues to optimize its patent strategy by prioritizing key jurisdictions and ensuring the continued expansion of its valuable patent portfolio.

- **IDWeek 2025** – Iterum will be conducting a Learning Lounge at IDWeek 2025 on Tuesday, October 21, 2025, in Atlanta, GA. The title of presentation is 'An Overview of Urinary Tract Infection in Adult Women: Focus on Oral Sulopenem.' Presenters: Steven I. Aronin, M.D. and Michael Dunne, M.D.

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 U.S. Food and Drug Administration approval for ORLYNVAH™ (oral sulopenem) for the treatment of uUTIs caused by *Escherichia coli*, *Klebsiella pneumoniae* or *Proteus mirabilis* in adult women with limited or no alternative oral antibacterial treatment options, and ORLYNVAH™ is commercially available in the United States. Iterum has also been granted 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 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 development, therapeutic and market potential of ORLYNVAH™ and the success of Iterum's commercialization of ORLYNVAH™ in the U.S. 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 Iterum's successful commercialization of ORLYNVAH™ in the U.S. with its commercial partner, EVERSANA, including Iterum's ability to maintain and continue to build a sales force for the commercialization of ORLYNVAH™ in the U.S., the ability of shareholders and other stakeholders to realize any value or recovery as part of a wind down process if the commercialization of ORLYNVAH™ in the U.S. is unsuccessful, 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 raise funds either through a capital raise and/or revenue generated from sales of ORLYNVAH™, the protection provided by Iterum's patents, 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, 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 for the quarterly period ended June 30, 2025 filed with the SEC on August 5, 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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Source: Iterum Therapeutics PLC