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Iterum Therapeutics launches ORLYNVAH™, the first and only oral penem antibiotic in the U.S.

FDA-approved antibiotic with the power of a penem in a novel oral formulation, offering a vital alternative in treating uncomplicated urinary tract infections

DUBLIN and CHICAGO, Aug. 20, 2025 (GLOBE NEWSWIRE) -- Iterum Therapeutics plc (Nasdaq: ITRM), 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 announced the U.S. commercial launch of ORLYNVAH™ (sulopenem etzadroxil and probenecid) oral tablets. The Food and Drug Administration (FDA) approved ORLYNVAH™ for adult women with uncomplicated urinary tract infections (uUTIs) caused by *Escherichia coli*, *Klebsiella pneumoniae* or *Proteus mirabilis* with limited or no alternative oral antibacterial options in October 2024. ORLYNVAH™ is the first oral penem antibiotic commercially available in the U.S. and the first new branded product to be introduced in the U.S. for uUTI in more than 25 years – offering a critical option for patients and physicians facing a shrinking arsenal of effective oral therapies.

Sixty percent of women experience a urinary tract infection in their lifetime and 44% experience three or more episodes annually. It is the most common outpatient infection in women in the United States, and resistance continues to increase. According to a 2024 U.S. study in approximately 150,000 patients with uncomplicated UTIs:

- 57% of initial infections were resistant to at least one antibiotic class; and
- 13% were resistant to three or more.

Without new, safe and effective oral therapies, resistant uUTIs are expected to inflate healthcare costs and may lead to poor patient outcomes in the U.S., including the need for additional courses of therapy, emergency room visits or hospitalizations, all of which underscore the urgent need for innovation in this space.

“The availability of ORLYNVAH™ is tremendous news for clinicians and patients alike,” said Marjorie Golden, MD, FIDSA, Site Chief, Infectious Disease, St. Raphael Campus Yale New Haven Hospital. “The launch of ORLYNVAH™ provides a new treatment option with impressive efficacy data to treat appropriate adult women suffering from difficult-to-treat uUTIs.” Dr. Golden added, “For patients who currently have limited treatment options, ORLYNVAH™ provides a long overdue oral alternative that allows for treatment in the community. This paradigm shift in the management of patients with uUTI will not only reduce emergency department visits and hospital admissions, but it will also favorably impact patients’ quality of life.”

“Our mission is to create new antibiotics for patients and to be a treatment alternative to address substantial unmet medical needs in the community,” said Corey Fishman, Chief Executive Officer of Iterum Therapeutics. “For many people with multidrug-resistant uUTIs, options have been exhausted. We’re proud to introduce ORLYNVAH™—the first oral penem ever approved by the FDA—giving clinicians and patients a much-needed new therapy.”

To support patient access, Iterum Therapeutics is launching a copay savings program allowing eligible patients to obtain ORLYNVAH™ for as little as $25. For more information about ORLYNVAH™, including full prescribing information, please visit **www.ORLYNVAH.com**.

Uncomplicated urinary tract infections (uUTIs) are a common bladder infection typically confined to the lower urinary tract in otherwise healthy women with no structural abnormalities of the urinary tract—caused by *Escherichia coli*, *Klebsiella pneumoniae* or *Proteus mirabilis*.

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 uncomplicated urinary tract infections (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, the potential impact of resistant uUTIs on healthcare costs and medical outcomes for uUTI patients in the U.S., 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 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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