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Iterum Therapeutics Presents Data Highlighting Antibiotic Sulopenem at IDWeek 2018

DUBLIN, Ireland and CHICAGO, Oct. 05, 2018 (GLOBE NEWSWIRE) -- Iterum Therapeutics plc (Nasdaq: ITRM), a clinical-stage pharmaceutical company developing antibiotics against multi-drug resistant pathogens, will present data on sulopenem, its novel oral and IV penem antibiotic, in three poster presentations today at IDWeek 2018 in San Francisco.

“The research we’re sharing at IDWeek 2018 underscores the need for new antibiotics, particularly oral therapies like sulopenem that can be used in both the community and hospital settings, and are effective against the resistant bacteria that are rendering current oral options ineffective,” said Michael Dunne, M.D., Chief Scientific Officer of Iterum Therapeutics. “With our Phase 3 clinical program now underway for oral sulopenem in uncomplicated urinary tract infections, and IV to oral sulopenem in complicated urinary tract infections and complicated intra-abdominal infections, we are closer to bringing the first oral penem antibiotic to the market to help address the growing multi-drug resistance crisis.”

Poster Number 1393

A Phase 1, Randomized, Open-Label, Crossover Study in Healthy Subjects under Fasting Conditions of Orally Administered Sulopenem Etzadroxil Alone or with Probenecid to Determine the Pharmacokinetics of Sulopenem

To assess the time above minimum inhibitory concentration (MIC), a key pharmacokinetic-pharmacodynamic variable correlating with efficacy for penem antibiotics, 12 healthy subjects were randomized to a single oral dose of 500 mg sulopenem etzadroxil alone or co-administered with a single oral dose of probenecid 500 mg in a crossover design. All doses were given under fasting conditions. Probenecid was found to increase the area under the curve (AUC) of sulopenem by 28 percent and extends the mean time over MIC.

Poster Number 1363

Sulopenem Activity against Enterobacteriaceae Isolates from Patients with Urinary Tract Infection or Intra-Abdominal Infection

The *in vitro* antibacterial activity of sulopenem was evaluated against clinical Enterobacteriaceae isolates from patients in North America with urinary tract infections (UTI) or complicated intra-abdominal infections (cIAI) collected during 2016 and 2017. Sulopenem demonstrated potent *in vitro* activity against organisms commonly implicated in UTI and cIAI, supporting further clinical development of sulopenem for gram-negative infections.

Poster Number 1527

The Prevalence of Enterobacteriaceae (ENT) Resistant to all Major Classes of Oral Antibiotics from Outpatient Urine Cultures in the United States and Effect on Clinical Outcomes

In the United States, as many as 21 million prescriptions for an uncomplicated urinary tract infection are written every year. In this retrospective study, antibiotic fill history was examined for patients with a positive ambulatory urine culture and further categorized into those with a pathogen either susceptible or non-susceptible to the prescribed antibiotic. Four percent of urine cultures had an Enterobacteriaceae that was resistant to at least three of the four major classes of oral antibiotics; one percent were resistant to all classes. Patients with mismatched antibiotic therapy were significantly more likely to require a second prescription or be hospitalized. Those patients with at least three-drug class resistance were three times more likely to require subsequent hospitalization.

The posters will be available on the Iterum website:https://www.iterumtx.com

About Iterum Therapeutics plc

Iterum Therapeutics plc is a clinical-stage pharmaceutical company dedicated to developing 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 sulopenem, a novel oral and IV penem anti-infective compound, in Phase 3 clinical development in uncomplicated urinary tract infection (uUTI), complicated urinary tract infection (cUTI) and complicated intra-abdominal infection (cIAI). Sulopenem is the first oral and IV penem to demonstrate potent *in vitro* activity against a wide variety of gram-negative, gram-positive and anaerobic bacteria that are resistant to other antibiotics in the hospital and community setting. Iterum has received QIDP designations for oral and IV sulopenem for the treatment of uUTI, cUTI and cIAI. For more information, please visit http://www.iterumtx.com.

Forward-looking Statements

This press release contains forward-looking statements. These forward-looking statements include, without limitation, statements regarding the development, therapeutic and market potential of sulopenem, the timing, progress and results of clinical trials, and the expected timing of NDA filings. 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,” “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 Therapeutics’ 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 Therapeutics’ control, including the uncertainties inherent in the initiation and conduct of clinical trials, clinical trial patient enrollment, availability and timing of data from clinical trials, changes in regulatory requirements or decisions of regulatory authorities, commercialization plans and timelines, if approved, the actions of third-party clinical research organizations, suppliers and manufacturers and other factors discussed under the caption “Risk Factors” in its Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (the “SEC”) on

August 14, 2018, and other documents filed with the SEC from time to time. Forward-looking statements represent Iterum Therapeutics' beliefs and assumptions only as of the date of this press release. Except as required by law, Iterum Therapeutics 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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