April 20, 2018

Iterum Therapeutics Presents Data on Prevalence of Resistant Infections and Activity of its Novel Antibiotic Sulopenem

More than 20 per cent of patients with outpatient urinary tract infections (UTIs) receive an antibiotic to which the responsible pathogen is not susceptible

Ineffective prescribing against resistant organisms greatly increases the need for a second antibiotic prescription and/or hospital admissions

Initial inappropriate antibiotic therapy for an outpatient UTI that results in a hospital admission is associated with an increase in the length of stay and total cost of care

Oral sulopenem provides potent antimicrobial activity in the urine

DUBLIN, April 20, 2018 /PRNewswire/ -- Iterum Therapeutics plc, a clinical-stage pharmaceutical company developing anti-infectives against multi-drug resistant pathogens, will deliver a mini-oral presentation and two additional posters at the European Congress of Clinical Microbiology in Madrid, Spain from April 21 to 24, 2018.

Mini-Oral Presentation of ePoster 0736

Impact of Initial Inappropriate Antibiotic Therapy on Outcome for Uncomplicated Urinary Tract Infection Due to Antibiotic Non-Susceptible Enterobacteriaceae

The authors reviewed the records of 4,792 patients given oral antibiotics for uUTIs. Data on culture susceptibility, patients requiring a second antibiotic, and hospitalizations were recorded. They concluded:

- Greater than 20% of patients with an outpatient UTI receive an antibiotic to which their pathogen is resistant
- Compared with episodes due to susceptible strains, prescribing an oral antibiotic to patients with outpatient UTI to which their pathogen is resistant is more likely to result in a second antibiotic prescription within 28 days and more than twice as likely to result in a hospitalization [(34% vs 19%, p<0.001; and 12.2% vs 5.6%, p <0.001, respectively)]
- The 28-day antibiotic re-fill rate did not differ significantly by baseline pathogen or initial antibiotic prescribed

Poster 1527

Antimicrobial Activity of Sulopenem in the Urine of Healthy Volunteers

- Bactericidal activity against all *E. coli* and *K. pneumoniae*, including the OXA-48 producing organism, was evident in all urine samples tested indicating potent antimicrobial activity of sulopenem in the urine
- Taking oral sulopenem with food resulted in higher sulopenem concentrations in the urine
- Concentrations of sulopenem in the urine remained above the MIC of target pathogens for the entire duration of dosing

Poster 2147

Impact of ESBL-Positivity and Quinolone Non-Susceptibility on Outcome for Inpatients with Complicated Urinary Tract Infections: A Multicenter Evaluation in the US

- Patients more likely to have cUTI caused by antibiotic resistant uropathogens are those with diabetes mellitus, renal failure and/or paralysis or admitted from long-term care or rehabilitation facilities
- Overall, patients with cUTI caused by resistant pathogens have a higher ICU admission rate and unadjusted mortality rate
- Prescription of inappropriate empiric antibiotic therapy was most frequently a result of β-lactam use and also observed in 29% of patients when quinolones are prescribed
- Inappropriate empiric antibiotic therapy resulted in an increase in length of stay and increased total cost of care

"*The finding that one-in-five uncomplicated UTIs is caused by a multi-drug resistant pathogen is significant and instructive," said Dr. Michael Dunne, chief scientific officer at Iterum Therapeutics. "These and other data clearly show the need for new clinical approaches and therapies against resistant pathogens that are rendering traditional oral antibiotics ineffective*."

"*We believe sulopenem, which is being developed in oral and intravenous forms, has considerable potential as an important new treatment option to help patients and physicians better address infections caused by resistant pathogens*."

Note to Editors:

About Iterum Therapeutics plc

Iterum Therapeutics plc (Iterum Therapeutics) is an Irish 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 Therapeutics is advancing its first compound, sulopenem, a novel penem anti-infective compound with oral and IV formulations that has demonstrated potent in vitro activity against a wide variety of gram-negative, gram-positive and anaerobic bacteria resistant to other antibiotics. Iterum Therapeutics has received QIDP designations for its oral and IV formulations for the treatment of uUTI, cUTI and cIAI. Iterum Therapeutics is led by a highly experienced team and backed by a blue-chip venture capital syndicate. For more information, please visit

http://www.iterumtx.com.

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