Iterum Therapeutics to Present Data on Prevalence of Resistant Infections and In Vitro Activity of its Novel Antibiotic Sulopenem

In U.S. patients, quinolone non-susceptibility seen in over 20 per cent of isolates from the urinary tract, driven primarily by resistance in E. coli and P. mirabilis

Patients with a quinolone resistant pathogen who received a quinolone for uncomplicated, outpatient urinary tract infections are twice as likely to require another antibiotic prescription or hospitalization

Sulopenem demonstrated potent in vitro activity against organisms commonly implicated in urinary tract and intra-abdominal infections

DUBLIN and CHICAGO, June 6, 2018 /PRNewswire/ -- Iterum Therapeutics plc (Nasdaq: ITRM), a clinical-stage pharmaceutical company developing anti-infectives against multi-drug resistant pathogens, will present four posters at the American Society of Microbiology MICROBE meeting in Atlanta from June 7 - 10, 2018.

Poster 695, June 8

Impact of Initial Inappropriate Antibiotic Therapy on Outcome for Outpatient Urinary Tract Infection Due to Fluoroquinolone Non-Susceptible Uropathogens

- In U.S. patients, quinolone non-susceptibility is seen in over 20 per cent of isolates from the urinary tract, driven primarily by resistance in E. coli and P. mirabilis.
- Over the subsequent 28 days, patients with a quinolone resistant pathogen who received a quinolone for an uncomplicated urinary tract infection were twice as likely to require another antibiotic prescription or be hospitalized and receive antibiotics.

Poster 569, June 10

Sulopenem Activity Against Enterobacteriacea Isolates from Patients with Urinary Tract Infection

- Sulopenem demonstrated potent in vitro activity against organisms commonly implicated in urinary tract and intra-abdominal infections, including those caused by
ESBL-producing or quinolone non-susceptible pathogens.

**Prediction of Sulopenem Activity Against Enterobacteriaceae Using Ertapenem as a Surrogate**

- Sulopenem demonstrated potent activity for *Enterobacteriaceae* with MIC$_{90}$ results ranging from 0.06 to 0.25 μg/mL for *E. coli*, *Klebsiella* species and *P. mirabilis*.
- It may be possible to use ertapenem susceptibility test results as a surrogate to predict sulopenem activity.
- Establishment of breakpoints for sulopenem will help better understand the potential clinical application of these findings.

**In Vitro Activity of Sulopenem, an Oral Penem, Against Escherichia coli Isolated from Urine Specimens of Patients Across Canada in 2014-2016**

- Sulopenem demonstrates potent *in vitro* activity against urinary isolates of *E. coli*.
- The *in vitro* activity of sulopenem against urinary isolates of *E.coli* was unaffected by concurrent non-susceptibility to trimethoprim-sulfamethoxazole or ciprofloxacin.
- The *in vitro* activity of sulopenem against urinary isolates of *E.coli* was unaffected by the presence of ESBL or AmpC enzymes, or MDR phenotypes.
- Sulopenem may represent a valuable treatment option for urinary *E. coli* with various antimicrobial resistance phenotypes, warranting further surveillance and clinical development.

"Quinolones, the most commonly prescribed class of antibiotics for treatment of uncomplicated urinary tract infections, are resulting in clinical failures at an alarming rate," said Michael Dunne, M.D., Chief Scientific Officer at Iterum Therapeutics. "Given the resistance to quinolones in the community, new treatment strategies, including new antibacterial therapies, are urgently needed."

"We believe sulopenem, with its spectrum of in vitro activity has considerable potential as an important new treatment option, in an oral and intravenous formulation, to help patients and physicians better address infections caused by resistant pathogens."

**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 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, complicated urinary tract infection and complicated intra-abdominal
infection. 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 and therapeutic potential of sulopenem and the timing, progress and results of clinical trials. 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 results of clinical trials, clinical trial patient enrolment, 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 the final prospectus for Iterum Therapeutics' initial public offering, which was filed with the Securities and Exchange Commission (the "SEC") on May 25, 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.

Contact:
Jeff Schaffnit
Chief Commercial Officer
312-778-6076
IR@iterumtx.com


SOURCE Iterum Therapeutics plc