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Iterum Announces Sulopenem in Development for Treatment of Gram-Negative, Multi-drug Resistant Infections

Oral and IV Formulation Broad-spectrum Antibiotic for Use in Hospital and Community Settings Granted Qualified Infectious Disease Product (QIDP) Designation by U.S. FDA

Initiation of Phase 3 Studies Expected by Year-End 2017

DUBLIN, IRELAND, and CHICAGO – January 5, 2017 – Iterum Therapeutics Limited, an Irish clinical-stage pharmaceutical company focused on the development and commercialization of anti-infectives for patients with infectious diseases and other acute illnesses, today announced that its first product candidate, sulopenem, a novel oral penem antibiotic, is under development for the treatment of multi-drug resistant infections. Sulopenem, with a safety and efficacy profile similar to other penems, has demonstrated broad-spectrum coverage and is highly effective against the pathogens most commonly associated with uncomplicated urinary tract infections, complicated urinary tract infections and complicated intra-abdominal infections (uUTI, cUTI and cIAI), including potent in-vitro activity against Enterobacteriaceae (ESBL) mutants of *E. coli* and *K. pneumonia*.

“The emergence and spread of drug-resistant and serious infections is increasing, and new antibiotics are needed. We believe sulopenem can effectively address the need for new therapies given the existing and projected resistance to generic antibiotic options, particularly fluoroquinolones, which are the most often used antibiotic class for urinary tract infections,” said Corey Fishman, Iterum’s CEO. “With both oral and IV options, sulopenem enhances the utility of penems, the ‘gold standard’ treatment of gram-negative infections. In the hospital setting, oral sulopenem will provide flexibility, allowing for simplified, effective step-down therapy upon patient discharge and potentially reducing the length of hospitalization. In the case of community-related infections, sulopenem will provide an efficacious treatment alternative, as well as the potential avoidance of hospitalization.”

Sulopenem was licensed from Pfizer in late 2015 and under the license agreement, Pfizer received an initial equity interest and an upfront cash payment from Iterum. Pfizer is also eligible to receive additional equity, development and commercial event-driven cash milestone payments and royalties based upon global net sales of any potential sulopenem products.

In the initial indications of interest, it is estimated that there are more than 25 million infections annually in the U.S. alone, with approximately 80 percent of those occurring in uUTI. Resistance to fluoroquinolones, currently a main treatment in uUTI, has become an issue in many parts of the country and is expected to continue to rise. Additionally, there have been no new treatments approved for uUTI in the last 20 years. “With very limited

products in late-stage development for uUTI, resistance rates to fluoroquinolones above 30 percent in some parts of the country and the strong profile of sulopenem, we believe that our new, unique oral agent will have a leading share of voice and be very well received in the marketplace," said Dr. Michael Dunne, Iterum's Chief Scientific Officer.

Sulopenem's global development efforts to date confirm its safety and efficacy, having been studied in more than 1,100 subjects in Japan with its IV formulation and a Phase 2a oral study in community-acquired pneumonia (CAP) in the U.S. Iterum anticipates commencing three Phase 3 studies under Special Protocol Assessment (SPA) with the United States Food and Drug Administration (FDA) and Scientific Advice from the European Medicines Agency (EMA) in the initial indications of uUTI, cUTI and cIAI by the end of 2017 and filing a new drug application (NDA) and marketing authorization application (MAA) in the second half of 2019.

As previously announced, Iterum secured a $40 million Series A financing in November 2015 from a syndicate of sophisticated life science investors. The round was led by Frazier Healthcare Partners and joined by Canaan Partners, Sofinnova Ventures and New Leaf Venture Partners. These investors also backed two previous companies (MedPointe Healthcare and Durata Therapeutics) that the Iterum team led, grew and successfully sold. "The Iterum team has made tremendous progress over the last 12 months since licensing this asset. We are very excited to continue development of this novel asset and ultimately bring a new, powerful agent to the marketplace that provides an effective option to treat both hospital and community infections," said Patrick Heron, managing general partner of Frazier Healthcare Partners.

Separately, the FDA has granted the QIDP designation to sulopenem for its oral and IV formulations for the treatment of uUTI, cUTI and cIAI. The QIDP designation will make sulopenem eligible to benefit from certain incentives for the development of new antibiotics provided under the Generating Antibiotic Incentives Now (GAIN) Act, which include priority review and fast-track status. Further, if approved, sulopenem would be eligible for an additional five-year extension of Hatch-Waxman exclusivity.

Iterum Therapeutics Limited
Iterum Therapeutics Limited 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 is advancing its first compound, sulopenem, a novel penem anti-infective compound with oral and IV formulations in an IV only class of antibiotics that 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 QIDP designations for its oral and IV formulations for the treatment of uUTI, cUTI and cIAI. Iterum is led by a highly experienced team and backed by a blue-chip venture capital syndicate including Canaan, Frazier, New Leaf and Sofinnova. For more information, please visit http://www.iterumtx.com.

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