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Iterum Therapeutics Announces Collaboration with EVERSANA to Support Oral Sulopenem Launch

DUBLIN, Ireland and CHICAGO, Feb. 01, 2021 (GLOBE NEWSWIRE) -- Iterum Therapeutics plc (Nasdaq: ITRM) (the Company), a clinical-stage pharmaceutical company focused on developing next generation oral and IV antibiotics to treat infections caused by multi-drug resistant pathogens in both community and hospital settings, today announced it has engaged EVERSANA™, a leading provider of commercial services to the life science industry, to immediately initiate pre-launch activities, followed by planned commercialization services upon final agreement.

As previously announced, the U.S. Food and Drug Administration (FDA) accepted for review the New Drug Application (NDA) for sulopenem etzadroxil/probenecid (oral sulopenem) for the treatment of uncomplicated urinary tract infections (uUTIs) in patients with a quinolone non-susceptible pathogen.

Ahead of an anticipated decision by the FDA in July 2021, Iterum will utilize EVERSANA's pre-launch activities including U.S. market access, strategic marketing, medical education, and patient services. Fully integrated commercialization services would then be expected to include clinical and commercial field teams, market access, channel management and distribution, health economics and outcomes research, compliance and medical science liaison teams, with each service optimized by data and predictive analytics. The agreement with EVERSANA builds on the strong commercial strategies the Company has developed over the last few years.

"We are very pleased to partner with EVERSANA and are confident in their ability to provide end-to-end services to ensure oral sulopenem will reach patients and their families efficiently and effectively once oral sulopenem is available for prescribing," said Corey Fishman, Chief Executive Officer at Iterum Therapeutics. "We will be working diligently to ensure we are ready for the potential launch of oral sulopenem in the U.S. in the fourth quarter of 2021."

"We believe in sulopenem's value to meet a long-standing, unmet clinical need and look forward to providing Iterum's patients with access to comprehensive support at launch using our ready-to-deploy complete commercialization infrastructure and experts," said Jim Lang, Chief Executive Officer of EVERSANA.

The FDA has designated the NDA for priority review and consequently assigned a PDUFA (Prescription Drug User Fee Act) goal date for completion of the review of oral sulopenem of July 25, 2021.

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, in Phase 3 clinical development 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 Therapeutics has received Qualified Infectious Disease Product (QIDP) and Fast Track designations for its oral and IV formulations of sulopenem in seven indications.

About EVERSANA

EVERSANA™ is the leading provider of global services to the life sciences industry. The company's integrated solutions are rooted in the patient experience and span all stages of the product life cycle to deliver long-term, sustainable value for patients, prescribers, channel partners and payers. The company serves more than 500 organizations, including innovative start-ups and established pharmaceutical companies, to advance life science solutions for a healthier world.

Forward-Looking Statements

This press release contains forward-looking statements. These forward-looking statements include, without limitation, statements regarding, among other things, entering into a final binding agreement with EVERSANA with respect to launch and future commercial services, including obtaining all necessary approvals that may be required, timing and outcome of the review of regulatory filings and the market opportunity for, and potential market acceptance of, oral sulopenem for uUTIs, and the Company's plans, strategies and prospects for its business. 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 the Company'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 the Company's control, including the uncertainties inherent in the initiation and conduct of clinical trials, availability and timing of data from clinical trials, changes in regulatory requirements or decisions of regulatory authorities, the timing of approval of any submission, changes in public policy or legislation, commercialization plans and timelines, if oral sulopenem is approved, the actions of third-party clinical research organizations, suppliers and manufacturers, the accuracy of the Company's expectations regarding how far into the future the Company's cash on hand will fund the Company's ongoing operations, the sufficiency of the Company's cash resources and the Company's ability to continue as a going concern, the impact of COVID-19 and related responsive measures thereto, the Company's ability to maintain listing on the Nasdaq Capital Market, risks and uncertainties concerning the outcome, impact, effects and results of the Company's evaluation of corporate, organizational, strategic, financial and financing alternatives, including the terms, timing, structure, value, benefits and costs of any corporate, organizational, strategic, financial or financing alternative and the Company's ability to complete one at all, the price of the Company's securities and other factors discussed under the caption "Risk Factors" in its most recently filed Quarterly Report on Form 10-Q, and other documents filed with the SEC

from time to time. Forward-looking statements represent the Company's beliefs and assumptions only as of the date of this press release. Except as required by law, the Company 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.

Iterum Therapeutics plc Investor Contact:

Judy Matthews

Chief Financial Officer 312-778-6073

IR@iterumtx.com

EVERSANA Media Contact:

Sarah Zwicky

Chief Marketing Officer +1 414-434-4691

sarah.zwicky@eversana.com



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