May 12, 2023

Iterum Therapeutics Reports First Quarter 2023 Financial Results

--Registration Trial for uUTI Ongoing and On Track--

--Cash Runway until Mid-2024--

DUBLIN, Ireland and CHICAGO, May 12, 2023 (GLOBE NEWSWIRE) -- Iterum Therapeutics plc (Nasdaq: ITRM) (Iterum), 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 reported financial results for the first quarter ended March 31, 2023.

“We remain on track to complete enrollment in our REASSURE trial in the first half of next year with over 100 sites currently open to enrollment and a plan to add another 40-70 clinical trial sites,” said Corey Fishman, Iterum’s Chief Executive Officer. “Top-line data is expected soon after enrollment is completed, with a potential resubmission of our new drug application (NDA) to the U.S. Food and Drug Administration (FDA) in the second half of 2024.”

Highlights and Recent Events

- **Enrollment in REASSURE Clinical Trial Ongoing:** Iterum began enrollment in its pivotal Phase 3 clinical trial, REASSURE (**RE**newed **AS**sessment of **S**ulopenem in u**U**TI caused by **R**esistant **E**nterobacterales), for the treatment of uncomplicated urinary tract infections (uUTI) in adult women in October 2022. Enrollment is ongoing and expected to be completed in the first half of 2024. An interim analysis at 50% patient enrollment is expected to occur in the second half of 2023. This trial is being conducted under a special protocol assessment (SPA) agreement with the FDA. The SPA agreement provides that the design and planned analysis of the trial, as set out in the protocol submitted to the FDA, adequately addresses the objectives necessary to support the potential resubmission of Iterum’s NDA for oral sulopenem for the treatment of uUTI.

- **Presented DOOR analysis at ECCMID:** Iterum presented scientific posters at ECCMID 2023 highlighting the application of the desirability of outcome ranking (DOOR) to two registration trials. The DOOR methodology, utilized recently by the Antibacterial Resistance Leadership Group to develop a method to evaluate data from completed pivotal complicated urinary tract infection (cUTI) trials, when applied retrospectively to Iterum’s two Phase 3 studies of sulopenem, one each in cUTI and uUTI, respectively, demonstrated that oral sulopenem was comparably more effective than ciprofloxacin in patients with uUTI and provided comparable efficacy to ertapenem in patients with cUTI. This novel method of analyzing data from clinical trials taking into account both benefits and harms of drugs being evaluated and providing an assessment of the patient experience has not yet been accepted by regulatory

authorities as a primary endpoint for UTI studies.

First Quarter 2023 Financial Results

Cash, cash equivalents and short-term investments were $51.8 million as of March 31, 2023. Based on the current operating plan, Iterum expects that its current cash, cash equivalents and short-term investments will be sufficient to fund its operations until mid-2024. As of April 30, 2023, we had approximately 12.9 million ordinary shares outstanding.

Research and development (R&D) expenses for the first quarter 2023 were $6.4 million, compared to $3.4 million for the same period in 2022. The increase for the three-month period was primarily due to an increase in costs to support our REASSURE trial, which began enrollment in October 2022, partially offset by a reduction in share-based compensation expense.

General and administrative (G&A) expenses for the first quarter 2023 were $2.1 million, compared to $3.9 million for the same period in 2022. The decrease for the three-month period was primarily due to a reduction in share-based compensation expense, as well as a decrease in legal fees associated with the lawsuit filed in August 2021 and dismissed with prejudice in January 2023.

Net loss for the first quarter 2023 was $9.9 million, compared to a net loss of $3.5 million for the same period in 2022. Non-GAAP[1] net loss for the first quarter 2023 of $7.4 million, compared to a non-GAAP1 net loss of $5.6 million for the same period in 2022.

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 currently advancing its first compound, sulopenem, a novel penem anti-infective compound, in Phase 3 clinical development with an oral formulation.
Sulopenem also has an 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 has received Qualified Infectious Disease Product (QIDP) and Fast Track designations for its oral and IV formulations of sulopenem in seven indications. For more information, please visit http://www.iterumtx.com.

Non-GAAP Financial Measures

To supplement Iterum's financial results presented in accordance with U.S. generally accepted accounting principles (GAAP), Iterum presents non-GAAP net loss and non-GAAP net loss per share to exclude from reported GAAP net loss and GAAP net loss per share, intangible asset amortization ($0.4 million); share-based compensation expense ($0.4 million); the interest expense associated with accrued interest on the Exchangeable Notes, payable in cash, shares or a combination of both upon exchange, redemption or at January 31, 2025 (the Maturity Date), whichever is earlier ($0.2 million); the non-cash amortization of the Exchangeable Notes ($0.6 million); and the non-cash adjustments to the fair value of derivatives and Royalty-Linked Notes ($0.9 million) for the three months ended March 31,

2023, and intangible asset amortization ($0.4 million); share-based compensation expense ($1.9 million); the interest expense associated with accrued interest on the Exchangeable Notes payable in cash, shares or a combination of both upon exchange, redemption or at the Maturity Date, whichever is earlier ($0.2 million); the non-cash amortization of the Exchangeable Notes ($0.6 million); and the non-cash adjustments to the fair value of derivatives and Royalty-Linked Notes ($5.2 million) for the three months ended March 31, 2022.

Iterum believes that the presentation of non-GAAP net loss and non-GAAP net loss per share, when viewed with its results under GAAP and the accompanying reconciliation, provides useful supplementary information to, and facilitates additional analysis by, investors, analysts, and Iterum's management in assessing Iterum's performance and results from period to period. These non-GAAP financial measures closely align with the way management measures and evaluates Iterum's performance. These non-GAAP financial measures should be considered in addition to, and not a substitute for, or superior to, net loss or other financial measures calculated in accordance with GAAP. Non-GAAP net loss and non-GAAP net loss per share are not based on any standardized methodology prescribed by GAAP and represents GAAP net loss, which is the most directly comparable GAAP measure, adjusted to exclude intangible asset amortization; share-based compensation expense; the interest expense associated with accrued interest on the Exchangeable Notes payable in cash, shares or a combination of both upon exchange, redemption or at the Maturity Date, whichever is earlier; the non-cash amortization of the Exchangeable Notes; and the non-cash adjustments to the fair value of derivatives and Royalty-Linked Notes for the three months ended March 31, 2023 and March 31, 2022. Because of the non-standardized definitions of non-GAAP financial measures, non-GAAP net loss and non-GAAP net loss per share used by Iterum in this press release and accompanying tables has limits in its usefulness to investors and may be calculated differently from, and therefore may not be directly comparable to, similarly titled measures used by other companies. A reconciliation of non-GAAP net loss to GAAP net loss and non-GAAP net loss per share to GAAP net loss per share have been provided in the tables included in this press release.

Special Note Regarding Forward Looking Statements

This press release contains forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. These forward-looking statements include, without limitation, statements regarding Iterum's plans, strategies and prospects for its business, including the development, therapeutic and market potential of sulopenem, the timing, conduct, progress and results of Iterum's ongoing REASSURE clinical trial, including the ability to open additional clinical sites and complete enrollment within the projected timeframe, the expected timing of resubmission of the NDA, and the sufficiency of Iterum's cash resources. 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 Iterum'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 Iterum's control, including uncertainties inherent in the design, initiation and conduct of clinical and non-clinical development, including the REASSURE clinical trial, availability and timing of data from the REASSURE clinical trial, changes in regulatory requirements or decisions of regulatory authorities, the timing or likelihood of regulatory filings and approvals, including the potential resubmission of the NDA for oral sulopenem, 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 Iterum's expectations regarding how far into the future Iterum's cash on hand will fund Iterum's ongoing operations, Iterum's ability to maintain its listing on the Nasdaq Capital Market, risks and uncertainties concerning the outcome, impact, effects and results of Iterum's evaluation of corporate, strategic, financial and financing alternatives, including the terms, timing, structure, value, benefits and costs of any corporate, strategic, financial or financing alternative and Iterum's ability to complete one at all and other factors discussed under the caption "Risk Factors" in its Annual Report on Form 10-K filed with the SEC on March 16, 2023, and other documents filed with the SEC from time to time. Forward-looking statements represent Iterum's beliefs and assumptions only as of the date of this press release. Except as required by law, Iterum 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.

Investor Contact:
Judy Matthews
Chief Financial Officer 312-778-6073
IR@iterumtx.com

[1] Definition and reconciliations of applicable GAAP reported to non-GAAP adjusted information are included at the end of this press release

ITERUM THERAPEUTICS PLC
Condensed Consolidated Statement of Operations
(In thousands except share and per share data)
(Unaudited)

	Three Months Ended March 31,	
	2023	**2022**
Operating expenses:		
Research and development	(6,432)	(3,440)
General and administrative	(2,098)	(3,933)
Total operating expenses	(8,530)	(7,373)
Operating loss	(8,530)	(7,373)
Interest expense, net	(399)	(1,039)
Adjustments to fair value of derivatives	(878)	5,177

Other income, net	41	162
Income tax expense	(123)	(427)
Net loss	$ (9,889)	$ (3,500)
Net loss per share – basic and diluted	$ (0.78)	$ (0.29)
Weighted average ordinary shares outstanding – basic and diluted	12,681,900	12,193,435
Reconciliation of non-GAAP net loss to GAAP net loss		
Net loss - GAAP	$ (9,889)	$ (3,500)
Intangible asset amortization	429	429
Share based compensation	393	1,895
Interest expense - accrued interest and amortization on Exchangeable Notes	783	783
Adjustments to fair value of derivatives	878	(5,177)
Non-GAAP net loss	$ (7,406)	$ (5,570)
Net loss per share - basic and diluted	$ (0.78)	$ (0.29)
Non-GAAP net loss per share - basic and diluted	$ (0.58)	$ (0.46)

ITERUM THERAPEUTICS PLC
Condensed Consolidated Balance Sheet Data
(In thousands)
(Unaudited)

	As of March 31, 2023	As of December 31, 2022
Cash, cash equivalents and short-term investments	$ 51,823	$ 60,804
Other assets	6,297	6,029
Total assets	**$ 58,120**	**$ 66,833**
Long-term debt, less current portion	$ 10,877	$ 10,094
Royalty-linked notes	19,258	18,372
Derivative liabilities	187	196
Other liabilities	8,841	10,172
Total liabilities	39,163	38,834
Total shareholders' equity	18,957	27,999
Total liabilities and shareholders' equity	**$ 58,120**	**$ 66,833**

Source: Iterum Therapeutics PLC