

iTeos Announces First Patient Dosed in GALAXIES Lung-301 Phase 3 Study, Earning \$35 Million in Milestones from GSK

July 8, 2024

WATERTOWN, Mass. and GOSSELIES, Belgium, July 08, 2024 (GLOBE NEWSWIRE) -- iTeos Therapeutics, Inc. (Nasdaq: ITOS) ("Teos"), a clinical-stage biopharmaceutical company pioneering the discovery and development of a new generation of immuno-oncology therapeutics for patients, today announced the dosing of the first patient in GALAXIES Lung-301, a global, randomized, double-blind Phase 3 registrational clinical trial of belrestotug + dostarlimab versus placebo + pembrolizumab in patients with first-line advanced, unresectable, or metastatic PD-L1 high NSCLC. This event has triggered \$35 million in development milestone payments from GSK, its partner for belrestotug.

"Dosing the first patient in the GALAXIES Lung-301 study marks a significant milestone for belrestotug + dostarlimab. iTeos was founded with the goal of advancing therapeutic options for patients by leveraging best-in-class science. The decision to launch our first TIGIT:PD-1 doublet Phase 3 trial underscores our disciplined, data-driven investment approach and was informed by several promising preliminary clinical surrogates such as safety, ORR, and depth of response from the latest interim analysis in May 2024," said Michel Detheux, Ph.D., president and chief executive officer of iTeos. "We are excited about the ongoing Phase 2 GALAXIES Lung-201 trial and look forward to presenting data from the most recent interim analysis of this study at a medical meeting in 2024."

iTeos and GSK entered into an exclusive development and commercialization collaboration in June 2021 for belrestotug, an anti-TIGIT monoclonal antibody, enabling novel next-generation immuno-oncology combinations. Per the agreement, iTeos received a \$625 million upfront payment from GSK with development and regulatory milestones up to \$550 million and commercial milestones up to \$900 million. In addition to the milestones, GSK and iTeos will jointly commercialize and equally split profits in the US. Outside the US, GSK will receive an exclusive license for commercialization and iTeos will receive tiered royalty payments. Within the collaboration, GSK and iTeos share responsibility and costs for the global development of belrestotug.

About iTeos Therapeutics, Inc.

iTeos Therapeutics is a clinical-stage biopharmaceutical company pioneering the discovery and development of a new generation of immuno-oncology therapeutics for patients. iTeos Therapeutics leverages its deep understanding of tumor immunology and immunosuppressive pathways to design novel product candidates with the potential to restore the immune response against cancer. The Company's innovative pipeline includes three clinical-stage programs targeting novel, validated immunosuppressive pathways designed with optimized pharmacologic properties for improved clinical outcomes, including the TIGIT/CD226 axis and the adenosine pathway. iTeos Therapeutics is headquartered in Watertown, MA with a research center in Gosselies, Belgium.

About Belrestotug (EOS-448/ GSK4428859A)

Belrestotug is an Fc active human immunoglobulin G1, or IgG1, monoclonal antibody (mAb) targeting T cell immunoglobulin and immunoreceptor tyrosine-based inhibitory motif domains (TIGIT), an important inhibitory receptor which contributes to the suppression of innate immune responses against cancer. As an optimized high-affinity, potent anti-TIGIT mAb, belrestotug is designed to enhance the antitumor response through a multifaceted immune modulatory mechanism by engaging with TIGIT and FcγR, a key regulator of immune responses which induces cytokine release and antibody dependent cellular cytotoxicity (ADCC). The therapeutic candidate is progressing in multiple indications in collaboration with GSK.

Internet Posting of Information

iTeos routinely posts information that may be important to investors in the 'Investors' section of its website at www.iteostherapeutics.com. The Company encourages investors and potential investors to consult our website regularly for important information about iTeos.

Forward-Looking Statements

This press release contains forward-looking statements. Any statements that are not solely statements of historical fact are forward-looking statements. Words such as "believe," "anticipate," "plan," "expect," "will," "may," "intend," "prepare," "look," "potential," "possible" and similar expressions are intended to identify forward-looking statements. These forward-looking statements include statements relating to the potential benefits of our product candidates and the expectation to present data from the most recent interim analysis of the Phase 2 GALAXIES Lung-201 trial at a medical meeting in 2024.

These forward-looking statements involve risks and uncertainties, many of which are beyond iTeos' control. Actual results could materially differ from those stated or implied by these forward-looking statements as a result of such risks and uncertainties. Known risk factors include the following: success in early clinical trials does not ensure that later clinical trials will be successful, and early results from a clinical trial do not necessarily predict final results; interim and early data may change as more patient data become available and are subject to audit and verification procedures; the expected benefits and opportunities related to the agreement between iTeos and GSK may not be realized or may take longer to realize due to a variety of reasons, including challenges and uncertainties inherent in product research and development and manufacturing limitations; and those risks identified under the heading "Risk Factors" in iTeos' Quarterly Report on Form 10-Q for the period ended March 31, 2024 filed with the Securities and Exchange Commission (SEC) as well as other SEC filings made by the Company which you are encouraged to review.

Any of the foregoing risks could materially and adversely affect iTeos' business, results of operations and the trading price of iTeos' common stock. We caution investors not to place undue reliance on the forward-looking statements contained in this press release. iTeos does not undertake any obligation to publicly update its forward-looking statements other than as required by law.

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