iTeos Announces 2025 Strategic Priorities and Anticipated Milestones

January 10, 2025

- Multiple TIGIT clinical data readouts anticipated throughout 2025, including >400 patients from two Phase 2 trials and one Phase 1/2 assessing belrestotug + dostarlimab in 1L NSCLC and 1L HNSCC

- EOS-984 Phase 1 monotherapy and PD-1 combination data anticipated in 2H25

- EOS-215, a potential best-in-class anti-TREM2 monoclonal antibody, IND submission anticipated in 1Q25

- Cash balance and investment balance of $683.9 million as of September 30, 2024 expected to provide runway through 2027

WATERTOWN, Mass. and GOSSELIES, Belgium, Jan. 10, 2025 (GLOBE NEWSWIRE) -- iTeos Therapeutics, Inc. (Nasdaq: ITOS), a clinical-stage biopharmaceutical company pioneering the discovery and development of a new generation of immuno-oncology therapeutics for patients, today outlined business updates and strategic priorities for 2025.

“As iTeos enters 2025, we are well-positioned to emerge as a leading oncology company by advancing therapies with first- or best-in-class potential that target resistance mechanisms within the tumor microenvironment. Starting in the second quarter, this year will feature robust TIGIT datasets in both non-small cell lung cancer and head and neck cancer, aiming to highlight the differentiation with our unique TIGIT:PD-1 doublet, belrestotug + dostarlimab. We are also excited about EOS-984 and EOS-215, our early-stage programs which demonstrate our track record of designing and developing innovative and differentiated therapies,” said Michel Detheux, Ph.D., president and chief executive officer of iTeos. “We look forward to a pivotal year for our company, with multiple data readouts and continued progress across our oncology portfolio.”

Program Highlights

Belrestotug (EOS-448/GSKFF28849A): IgG1 anti-TIGIT monoclonal antibody in development for the first-line treatment of locally advanced or metastatic PD-L1-high non-small cell lung cancer (NSCLC) and for the first-line treatment of PD-L1 positive recurrent/metastatic head and neck squamous cell carcinoma (HNSCC) in collaboration with GSK.

- **GALAXIES Lung-301**
  - Enrollment ongoing globally in randomized, double-blind Phase 3 registrational study assessing belrestotug + dostarlimab versus placebo + pembrolizumab in patients with first-line advanced, unresectable, or metastatic PD-L1 high NSCLC
  - Food and Drug Administration (FDA) and The National Medical Products Administration (NMPA) granted clearance to advance belrestotug 400mg + dostarlimab as the recommended Phase 3 dose, allowing for the activation of clinical sites in the U.S. and China, respectively.

- **GALAXIES Lung-201**
  - Topline interim data from Phase 2 platform study assessing belrestotug + dostarlimab doublet and a triplet with GSK’s investigational anti-CD96 antibody, nelistotug, in first-line advanced / metastatic PD-L1 high NSCLC anticipated in 2Q25 to include safety, ORR, and ctDNA data from >240 patients, with pembrolizumab monotherapy ORR for 30 patients and PFS data from initial 124 patients treated. Data are expected to be submitted for presentation at a scientific congress in 2H 2025.

- **GALAXIES H&N-202**
  - Interim data from Phase 2 platform study assessing belrestotug + dostarlimab doublet and triplet with nelistotug in first-line patients with PD-L1 positive recurrent/metastatic HNSCC anticipated in 2025 to include safety and ORR from >150 patients.

- **TIG-006 HNSCC**
  - Topline data from the TIG-006 study in cohorts 2C & 2D assessing belrestotug + dostarlimab doublet in first-line PD-L1 positive advanced / metastatic HNSCC anticipated in 2025 to include safety, ORR, and PFS from a total of 42 patients.

EOS-984: Potential first-in-class small molecule in oncology inhibiting ENT1, a dominant transporter of adenosine involved in T cell metabolism, expansion, effector function, and survival.

- **APT-008**
  - Topline data assessing EOS-984 as a monotherapy and in combination with pembrolizumab in patients with advanced solid tumors anticipated in 2H25.

EOS-215: Potential best-in-class anti-TREM2 with a novel mechanism of action blocking monoclonal antibody targeting tumor-associated macrophages to reprogram the tumor microenvironment.

- **TRM-010**
  - Investigative New Drug (IND) application for EOS-215 anticipated in 1Q25.

Financial Updates

Cash Position: The Company's cash and cash equivalent position was $683.9 million as of September 30, 2024, inclusive of a $35.0 million milestone received relating to the dosing of the first patient in the GALAXIES Lung-301 clinical trial. The Company expects its cash balance to provide runway through 2027, which includes the potential initiation of multiple Phase 3 registrational trials assessing belrestotug + dostarlimab doublet.

About iTeos Therapeutics, Inc.
Teos 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. 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 adaptive and 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.

About EOS-984
EOS-984 is a potential first-in-class small molecule targeting equilibrative nucleoside transporter 1 (ENT1) designed to inhibit the immunosuppressive activity of adenosine and restore immune cell proliferation. The therapeutic candidate has the potential to fully reverse the profound immunosuppressive action of adenosine on T and B cells and is in Phase 1 development.

About EOS-215
EOS-215 is a potential best-in-class monoclonal antibody which blocks ligand binding to triggering receptor expressed on myeloid cells 2 (TREM2), switching off multiple tumor growth and survival promoting activities of tumor resident macrophages and effectively “reprogramming” the macrophages to allow for T cell activation. The therapeutic candidate has shown activity in both *in vitro* and *in vivo* highly immune resistant models and is currently in IND-enabling studies.

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; iTeos being well-positioned to emerge as a leading oncology company by advancing therapies with first- or best-in-class potential that target resistance mechanisms within the tumor microenvironment; our plans and expected milestones, including having topline interim data from GALAXIES Lung-201 in 2Q25 that includes safety, ORR, and ctDNA data from > 240 patients, with pembrolizumab monotherapy ORR for 30 patients and PFS data from initial 124 patients treated, our expectation to submit data from GALAXIES Lung-201 for presentation at a scientific congress in 2H 2025, having interim data from GALAXIES H&N-202 in 2Q25 that include safety and ORR from a total of >150 patients, our expectation to submit the GALAXIES H&N-202 data for presentation at a scientific congress in 2H25, having topline data from the first portion of TIG-006 study in cohorts 2C & 2D in 2HQ25 that include safety, ORR, and PFS from a total of 40 patients, having topline data from EOS-984 in 2H25, our expectation to submit an IND for EOS-215 in 1Q25; and our expectation that 2025 will be a pivotal year, with multiple data readouts and continued progress across our oncology portfolio.

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: 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 any inability of the parties to perform their commitments and obligations under the agreement, challenges and uncertainties inherent in product research and development and manufacturing limitations; success in preclinical testing and 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 data for our product candidates may not be sufficient for obtaining regulatory approval to move into later stage trials or to commercialize products; iTeos may encounter unanticipated costs or may expend cash more rapidly or more slowly than currently anticipated due to challenges and uncertainties inherent in product research and development and biologics manufacturing; iTeos may not be able to execute on its business plans, including meeting its expected or planned regulatory milestones and timelines, research and clinical development plans, and bringing its product candidates to market, for various reasons, some of which may be outside of iTeos’ control, including possible limitations of company financial and other resources, manufacturing limitations that may not be anticipated or resolved for in a timely manner, negative developments in the field of immuno-oncology, such as adverse events or disappointing results, including in connection with competitor therapies, and regulatory, court or agency decisions such as decisions by the United States Patent and Trademark Office with respect to patents that cover our product candidates; and those risks identified under the heading “Risk Factors” in iTeos’ Annual Report on Form 10-Q for the period ended September 30, 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. Statements regarding the Company’s cash runway do not indicate when or if the Company may access the capital markets.

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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