iTeos Announces Clinically Meaningful Objective Response Rate Observed at Every Dose in Follow-up Interim Analysis of GALAXIES Lung-201 Study of Belrestotug + Dostarlimab in First-Line, PD-L1 High Non-Small Cell Lung Cancer Patients

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- Clinically meaningful objective response rate (ORR) of 63.3-76.7% observed with belrestotug + dostarlimab combinations, with confirmed ORR (cORR) at ~60% for every dose
- >30% cORR difference between belrestotug + dostarlimab vs dostarlimab monotherapy
- Belrestotug + dostarlimab safety profile broadly consistent with known safety profile of checkpoint inhibitor combinations
- GALAXIES Lung-301, global Phase 3 registration study, enrolling in same indication and setting
- iTeos to host a conference call on Monday, September 16, 2024 at 8:00am ET

WATERTOWN, Mass. and GOSSELIES, Belgium, Sept. 14, 2024 (GLOBE NEWSWIRE) -- iTeos Therapeutics, Inc. (Nasdaq: ITOS) ("iTeos"), a clinical-stage biopharmaceutical company pioneering the discovery and development of a new generation of immuno-oncology therapeutics for patients, today announced follow-up interim data from GALAXIES Lung-201, the Phase 2 platform study sponsored by iTeos' development partner GSK, assessing the belrestotug + dostarlimab doublet in previously untreated, unresectable, locally advanced or metastatic PD-L1 high non-small cell lung cancer (NSCLC).

"We are encouraged by this interim cut of GALAXIES Lung-201 data in which a clinically meaningful, investigator-assessed Objective Response Rate was observed with belrestotug in combination with dostarlimab in first-line, PD-L1 high non-small cell lung cancer patients. Further, with roughly 60 percent confirmed ORR at three distinct doses and a meaningful difference of 30 percent compared to dostarlimab alone, we believe this underscores the potential differentiation of our TIGIT:PD-1 doublet," said Michel Detheux, Ph.D., president and chief executive officer of iTeos. "The improvement in depth of response in tumor measurement in patients treated with the doublet compared to those treated with PD-1 alone holds promising therapeutic potential for a patient population with limited options. We believe these encouraging data further support the recent initiation of GALAXIES Lung-301, the registrational Phase 3 trial assessing the TIGIT:PD-1 doublet in the same indication and setting. Based on these results, we are committed to leveraging our science to impact the lives of people living with cancer and are excited to see longer-term follow-up data in 2025."

"While checkpoint inhibitor therapies have played a significant role in how we treat non-small cell lung cancer, the medical community continues to look for new patient-centered treatment options to meaningfully improve this life-threatening condition," said Brian Henick, M.D., interim director of experimental therapeutics and director of translational research in upper-aerodigestive malignancies in medical oncology of Columbia University Irving Medical Center. "The follow-up interim analysis from the GALAXIES Lung-201 study represent promising progress and the deep responses observed in the belrestotug + dostarlimab doublet provide a strong, consistent signal. We eagerly anticipate gaining further insights from this trial over the next year as the dataset matures."

Highlights of Interim GALAXIES Lung-201 Data
As of the June 7, 2024 data cutoff, the late-breaking interim data presented at the ESMO Congress were based on 124 patients eligible for safety and efficacy evaluation (modified intention-to-treat ≥5.6 months follow-up). Patients received dostarlimab or belrestotug + dostarlimab at the following dose levels: dostarlimab 500mg, belrestotug 100mg + dostarlimab 500mg (Dose A), belrestotug 400mg + dostarlimab 500mg (Dose B), and belrestotug 1000mg + dostarlimab 500mg (Dose C).

- Clinically meaningful improvement in the primary endpoint of ORR was observed consistently across each belrestotug + dostarlimab cohort (63.3% Dose A, 65.6% Dose B and 76.7% Dose C compared to 37.5% with dostarlimab alone). cORR, defined as complete or partial response confirmed by repeat imaging ≥4 weeks after response criteria first met, was roughly 60.0% for each dose compared to 28.1% cORR for dostarlimab alone.
- Of the patients with evaluable paired ctDNA samples (baseline and week 7), median ctDNA reduction was 65% for dostarlimab monotherapy compared to 55% for Dose A, 94% for Dose B, and 97% for Dose C.
- Belrestotug + dostarlimab led to an increase in immune-related adverse events compared to dostarlimab monotherapy, which were generally manageable. The safety profile of belrestotug in combination with dostarlimab has been broadly consistent with the known safety profile of combination therapy with checkpoint inhibitors. The most frequent treatment-related adverse events (≥15%) were skin and subcutaneous tissue disorders (50%) and endocrine disorders (26%), both commonly observed with immunotherapies.

Response measure in mITT	**Dostarlimab (N=32)**	**Dose A: Dostarlimab + belrestotug 100 mg (N=30)**	**Dose B: Dostarlimab + belrestotug 400 mg (N=32)**	**Dose C: Dostarimab + belrestotug 1000 mg (N=30)**
Median follow-up, months (range)	**7.0 (0.2–16.6)**	**8.5 (0.3–14.3)**	**8.5 (0.4–16.2)**	**6.7 (2.4–9.7)**
ORR,[1,2]% n (95% CI)	**37.5%** n=12 (21.1–56.3)	**63.3%** n=19 (43.9–80.1)	**65.6%** n=21 (46.8–81.4)	**76.7%** n=23 (57.7–90.1)
Complete response, n (%)	0	0	0	0

Partial response, n (%)	12 (37.5%)	19 (63.3%)	21 (65.6%)	23 (76.7%)
Stable disease, n (%)	14 (43.8%)	5 (16.7%)	4 (12.5%)	5 (16.7%)
Progressive disease, n (%)	2 (6.3%)	4 (13.3%)	3 (9.4%)	2 (6.7%)
Not evaluable/no assessment,[3] n (%)	4 (12.5%)	2 (6.7%)	4 (12.5%)	0
Confirmed ORR,[2] % n (95% CI)	**28.1%** n=9 (13.7–46.7)	**60.0%** n=18 (40.6–77.3)	**59.4%** n=19 (40.6–76.3)	**63.3%** n=19 (43.9–80.1)

1. unconfirmed ORR; 2. PD-L1 high (TPS ≥50%) was determined locally or centrally by DAKO 22C3 or VENTANA SP263 assay; 3. patients who only had "not evaluable" post baseline assessments, those who had a best response of "not evaluable" per RECIST 1.1 criteria, or those where no post-baseline tumor assessment was performed; CI, confidence interval

Conference Call Details
The follow-up interim data from GALAXIES Lung-201 will be discussed during a conference call and webcast presentation on Monday, September 16th, 2024 at 8:00AM ET. To register for the webcast presentation, please visit the Events section on the Investors page of the iTeos website at investors.iteostherapeutics.com. A webcast replay may be accessed on the Investors section of the iTeos website.

Phase 2 GALAXIES Lung-201 Trial Design
The Phase 2 GALAXIES Lung-201 study is a randomized, open-label, global platform study evaluating the efficacy, safety, pharmacokinetics, and pharmacodynamics of novel immunotherapy combinations compared with immunotherapy monotherapy in participants with PD-L1 high (TPS ≥50%), previously untreated, unresectable, locally advanced or metastatic NSCLC. Arms and interventions in this study include: pembrolizumab (anti-PD-1) monotherapy, dostarlimab (anti-PD-1) monotherapy, belrestotug (anti-TIGIT) + dostarlimab doublet combination, and belrestotug + dostarlimab + nelistotug (anti-CD96) triplet combination.

The primary endpoint of the study is investigator-assessed ORR per Response Evaluation Criteria in Solid Tumors (RECIST 1.1). Secondary endpoints include safety and additional efficacy measures such as progression free survival, overall survival, and duration of response.

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 and adaptive 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 belrestotug and the potential differentiation of belrestotug + dostarlimab; belrestotug's market opportunity; and our plans and expected milestones, including having longer-term follow-up data from GALAXIES Lung-201 in 2025.

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 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 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 June 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.

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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