UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): September 14, 2024

iTeos Therapeutics, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-39401**	**84-3365066**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

321 Arsenal Street **Watertown , Massachusetts**	**02472**
(Address of Principal Executive Offices)	**(Zip Code)**

Registrant's Telephone Number, Including Area Code: 339 217 0161

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, $0.001 par value per share	ITOS	The Nasdaq Global Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01 Regulation FD Disclosure.

On September 14, 2024, iTeos Therapeutics, Inc. (the "Company") issued a press release announcing additional interim clinical data from GALAXIES Lung-201, the Phase 2 platform study sponsored by the Company's development partner GSK plc, assessing the belrestotug + dostarlimab doublet in previously untreated, unresectable, locally advanced or metastatic PD-L1 high non-small cell lung cancer, a copy of which is furnished herewith as Exhibit 99.1 to this Current Report on Form 8-K. The Company will host a conference call to discuss the interim clinical data on September 16, 2024 at 8:00 a.m. E.T. A copy of the slide presentation that will accompany the call is being furnished as Exhibit 99.2 to this Current Report on Form 8-K. The Company undertakes no obligation to update, supplement or amend the materials attached hereto as Exhibits 99.1 or 99.2.

The information in this Item 7.01 is furnished pursuant to Item 7.01 and shall not be deemed "filed" for the purposes of Section 18 of the Securities and Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section. It may only be incorporated by reference in another filing under the Exchange Act or the Securities Act of 1933, as amended, if such subsequent filing specifically references the information furnished pursuant to Item 7.01 of this report.

Item 9.01 Financial Statements and Exhibits.

Exhibit No.	Description
99.1	Press release issued by iTeos Therapeutics, Inc. on September 14, 2024, furnished herewith
99.2	Corporate presentation, dated September 14, 2024, furnished herewith
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

iTeos Therapeutics, Inc.

Date: September 16, 2024

By: /s/ Michel Detheux

Michel Detheux, Ph.D.
President and Chief Executive Officer

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

- 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, September 14, 2024 -- 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.

For further information, please contact:

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iTEOS THERAPEUTICS

Cancer Immunotherapies by *design*™

GALAXIES Lung-201 Update

ESMO 2024

Forward-Looking Statements

This presentation 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; our plans and expected milestones, including having longer-term follow-up data from GALAXIES Lung-201 in 2025 and having data from the Phase 2 TIG-006 and GALAXIES H&N-202 in 2025; and our expectation to have cash runway through 2027.

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 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 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. 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.

Introduction

Michel Detheux, PhD

Chief Executive Officer & President

GALAXIES Lung-201Follow-up Interim Analysis

Outcomes And Actions

Study Scope

- **Population:** Unresectable locally advanced/metastatic PD-L1 high 1L NSCLC
- **Primary Endpoint**: ORR[1] per RECIST 1.1 by investigator assessment
- **Follow-Up Interim Data**: Clinically meaningful anti-tumor activity by belrestotug + dostarlimab at all doses vs dostarlimab monotherapy

Key Observations

- Belrestotug + dostarlimab combinations observed clinically meaningful ORR of 63.3-76.7%, with 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
- Numerically greater reduction of ctDNA associated with belrestotug 400mg and 100mg + dostarlimab cohorts

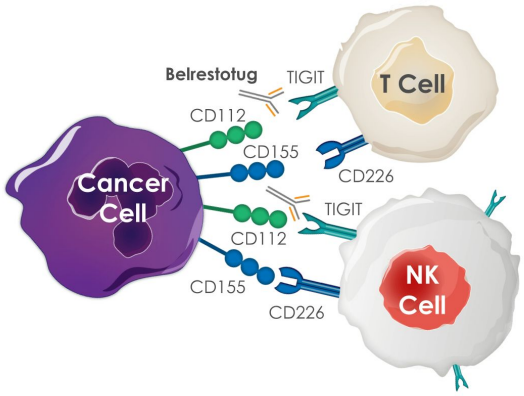
Next Steps

GALAXIES Lung-201:
Longer-term follow-up data in 2025

GALAXIES Lung-301:
Enrolling

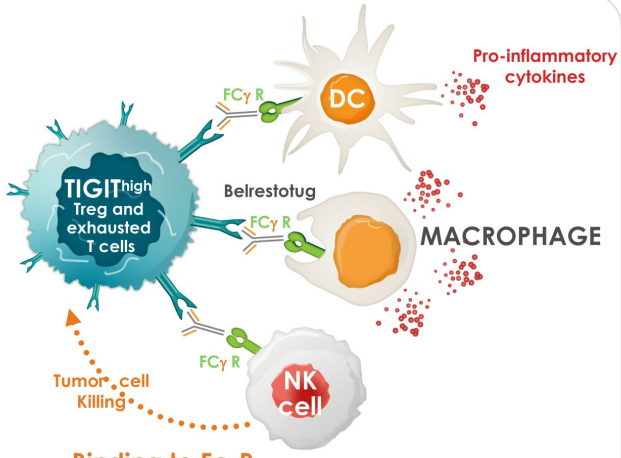
1. Unconfirmed; NSCLC, non-small cell lung cancer; Q3W, every 3 weeks; ORR, objective response rate; coRR, confirmed objective response rate; RECIST, Response Evaluation Criteria in Solid Tumours; PFS, progression free survival; AE, adverse event

Belrestotug: Designed to Enhance the Anti-Tumor Response through Activation of Multiple Immune Cells



1 **Binding to TIGIT**

Optimized affinity and potency to inhibit the suppressive function of TIGIT and to activate T cell and NK cell killing of tumor cells



2 **Binding to FcγR**

Pro-inflammatory cytokine release and activation of antigen-presenting cells (DCs and macrophages)

Depletion of Tregs and exhausted T cells allows for enhanced anti-tumor response

DC, dendritic cell; NK, natural killer; Tregs, regulatory T cells

Belrestotug: The First And Only TIGIT to Demonstrate Robust Target Engagement

Unique Epitope Binding

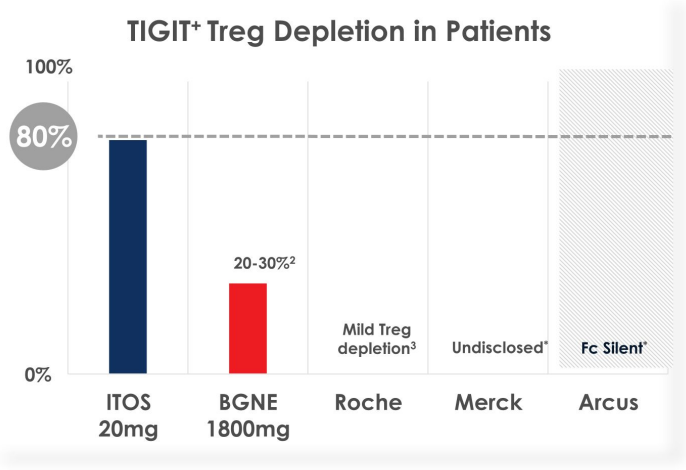
High Affinity + Potency

First and only TIGIT with proven

Treg depletion at all doses[1]

Only TIGIT to Demonstrate Phase 1

Monotherapy Activity[1]



*Merck vibostolimab has yet to publicly show Treg depletion data; Arcus' domvanalimab is an Fc silent TIGIT and not capable of Treg depletion

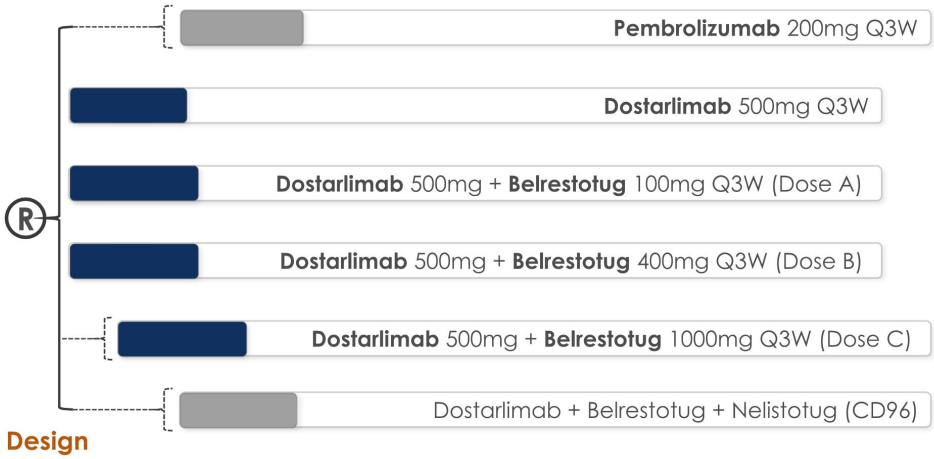
1. iTeos AACR 2021
2. doi: 10.1136/jitc-2022-SITC2022.0768
3. doi: 10.1038/s41586-024-07121-9

GALAXIES Lung-201 Follow-Up Interim Analysis

David Feltquate, MD
Chief Medical Officer

GALAXIES Lung-201 - Phase 2 in 1L NSCLC

The largest TIGIT Phase 2 in PD-L1 high 1L NSCLC



Key

R Subjects Randomization

Study Design

Estimated Enrollment 300

Status	Enrolling	**Objectives**	Evaluate belrestotug + dostarlimab safety, efficacy, PK/PD
Masking	Open label	**Primary Endpoint**	ORR
PDL1 Expression	≥50%	**Secondary Endpoint**	PFS, OS, DOR
Lines of Therapy	No prior systemic therapy	**Clinical Trials Listing**	NCT05565378
Delivery	IV Infusion		

NSCLC, non-small cell lung cancer; Q3W, every 3 weeks; ORR, overall response rate; PFS, progression free survival; OS, overall survival; DOR, duration of response

Baseline Characteristics Were Balanced Across Arms, with a Few Notable Differences in TIGIT:PD-1 Doublet Arms

Characteristic, n (%)	Dostarlimab N=32	A: Belrestotug 100 mg + dostarlimab N=30	B: Belrestotug 400 mg + dostarlimab N=32	C: Belrestotug 1000 mg + dostarlimab N=30
Male	**26 (81%)**	**18 (60%)**	**26 (81%)**	**16 (53%)**
Years of age, median (range)	69.0 (37–86)	68.5 (45–79)	67.0 (50–78)	68.0 (47–83)
Race				
White	24 (75%)	17 (61%)	18 (58%)	19 (70%)
Asian	5 (16%)	7 (25%)	10 (32%)	6 (22%)
ECOG PS[1] 1, n (%)	**11 (34%)**	**20 (67%)**	**16 (50%)**	**18 (60%)**
Stage III[1]	4 (12.5%)	7 (23.3%)	5 (15.6%)	3 (10%)
Stage IVa[1]	18 (56%)	8 (27%)	12 (38%)	17 (57%)
Stage IVb[1]	10 (31%)	15 (50%)	15 (47%)	10 (33%)
Squamous[2]	11 (34%)	11 (37%)	13 (41%)	9 (30%)
PD-L1 TPS ≥50%[3]	32 (100%)	30 (100%)	32 (100%)	29 (97%)[4]
Central PD-L1 TPS ≥90%[5]	12 (38%)	11 (37%)	12 (38%)	11 (37%)
Metastases at baseline				
Bone	**5 (16%)**	**7 (23%)**	**5 (16%)**	**4 (13%)**
Brain	**3 (9%)**	**4 (13%)**	**3 (9%)**	**3 (10%)**
Liver	**3 (9%)**	**6 (20%)**	**3 (9%)**	**0**

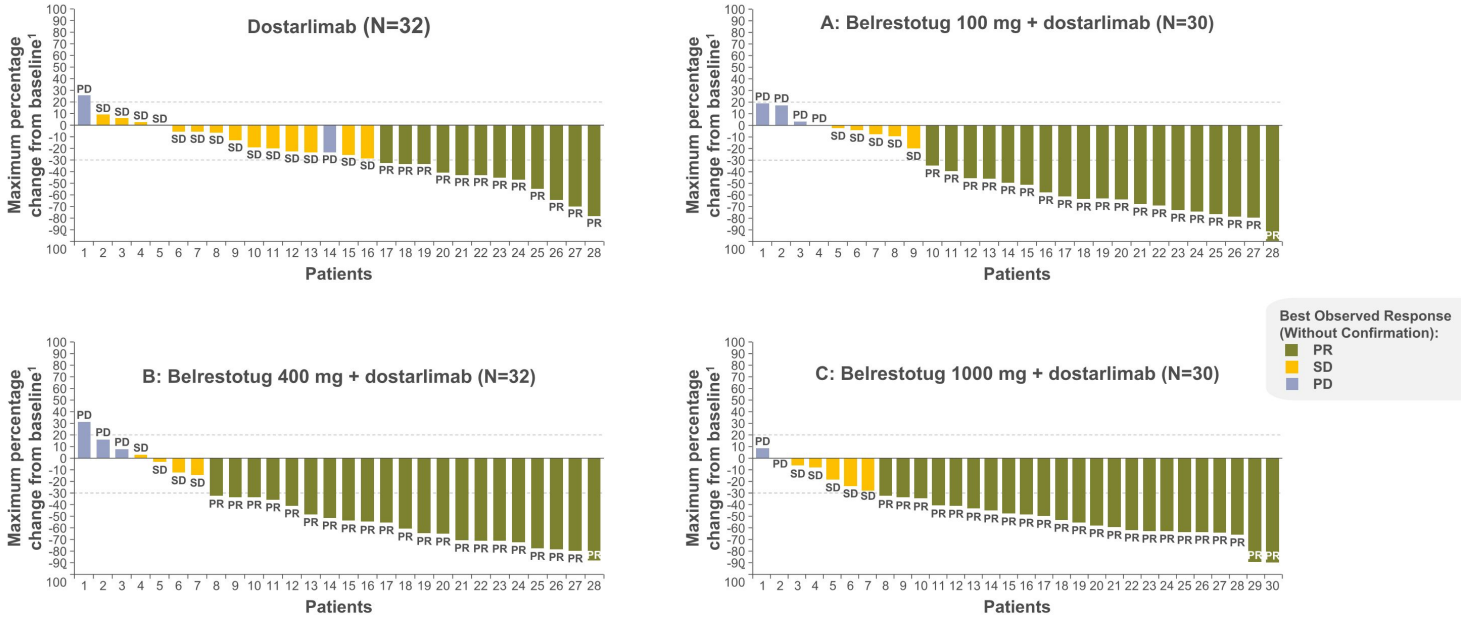
[1]At screening; [2]stratification factor; [3]PD-L1 high (TPS ≥50%) was determined locally or centrally by DAKO 22C3 or VENTANA SP263 assay; [4]one patient was enrolled with a PD-L1 <50%, a protocol deviation was noted; [5]PD-L1 TPS ≥90% was determined centrally using the VENTANA SP263 assay. ECOG PS, Eastern Cooperative Oncology Group performance status; PD-L1, programmed death ligand-1; TPS, tumour positive score.

Clinically Meaningful ORR Observed at Every Dose vs Dostarlimab Monotherapy

Response measure in mITT	Dostarlimab N=32	A: Belrestotug 100 mg + dostarlimab N=30	B: Belrestotug 400 mg + dostarlimab N=32	C: Belrestotug 1000 mg + dostarlimab N=30
Median follow-up, months (range)[1]	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,[2,3] **%** 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,[4] n (%)	4 (12.5%)	2 (6.7%)	4 (12.5%)	0
Confirmed ORR,[3,5] **%** 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)

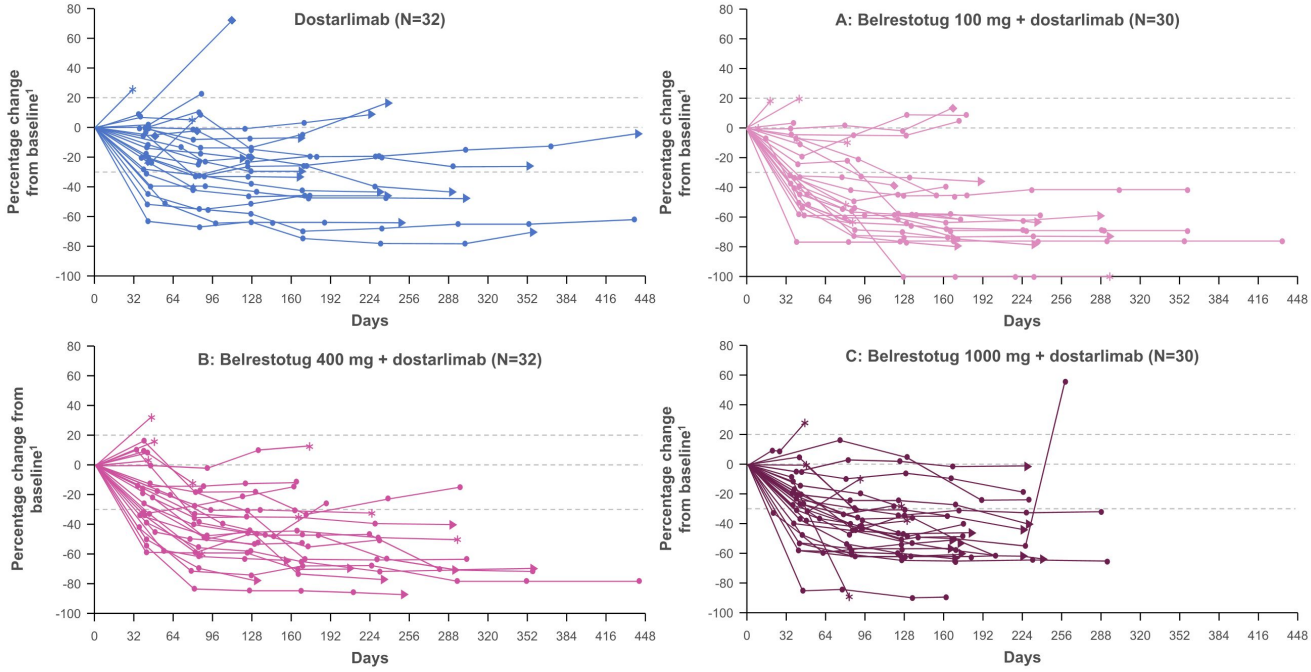
[1]As of data cut 7 Jun 2024, 65% of patients remained in ongoing follow-up; [2]unconfirmed ORR; [3]PD-L1 high (TPS ≥50%) was determined locally or centrally by DAKO 22C3 or VENTANA SP263 assay; [4]patients who only had "not evaluable" post-baseline assessments, those who had a best response of "not evaluable" per RECIST 1.1 by investigator assessment, or those where no post-baseline tumour assessment was performed; [5]complete or partial response confirmed by repeat imaging ≥4 weeks after response criteria first met. CI, confidence interval; mITT, modified intention-to-treat; ORR, objective response rate; PD-L1, programmed death ligand-1; RECIST, Response Evaluation Criteria in Solid Tumours; TPS, tumour positive score.

Belrestotug + Dostarlimab Consistently Increased Depth of Response vs Dostarlimab Monotherapy



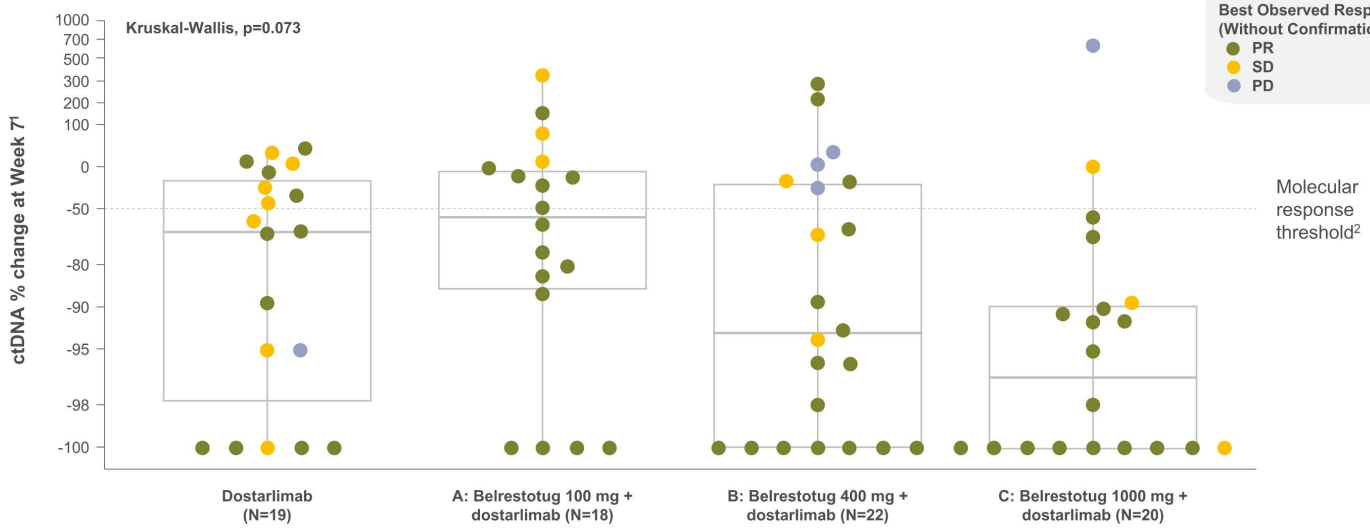
[1]Numerically lowest percent change from baseline that is on or prior to date of first radiological PD and start of follow-up anticancer therapy (excluding radiotherapy and surgery); patients without assessable post-baseline scans or where all baseline target lesions are not measured at subsequent visits are not included in figure; responses shown are per RECIST 1.1 by investigator assessment without confirmation. PD, progressive disease; PR, partial response; RECIST, Response Evaluation Criteria in Solid Tumours; SD, stable disease.

Consistent Deep Tumor Reduction with Ongoing Responses by Belrestotug + Dostarlimab vs Dostarlimab Monotherapy



[1]Investigator assessed percentage change from baseline per RECIST 1.1 by investigator assessment. RECIST, Response Evaluation Criteria in Solid Tumors.

Numerically Greater Reduction of ctDNA Associated with Belrestotug 400mg and 1000mg + Dostarlimab Cohorts



	Dostarlimab (N=19)	A: Belrestotug 100 mg + dostarlimab (N=18)	B: Belrestotug 400 mg + dostarlimab (N=22)	C: Belrestotug 1000 mg + dostarlimab (N=20)
Molecular Response Rate (>-50% from Baseline)	11/19 (58%)	9/18 (50%)	15/22 (68%)	18/20 (90%)
Median ctDNA % Change	-65%	-55%	-94%	-97%

[1]Mean variant allele frequency change from baseline to Week 7; [2]molecular response threshold defined as having at least 50% reduction of ctDNA levels. Responses shown are per RECIST 1.1 by investigator assessment without confirmation. ctDNA, circulating tumour DNA; PD, progressive disease; PR, partial response; RECIST, Response Evaluation Criteria in Solid Tumours; SD, stable disease.

Belrestotug + Dostarlimab Is Broadly Consistent with Known Safety Profile of Checkpoint Inhibitor Combinations

Increase in immune-related adverse events with belrestotug + dostarlimab vs dostarlimab

Event, n (%)	Dostarlimab (N=32)	A: Belrestotug 100 mg + dostarlimab (N=30)	B: Belrestotug 400 mg + dostarlimab (N=32)	C: Belrestotug 1000 mg + dostarlimab (N=30)
TEAE	29 (91%)	29 (97%)	31 (97%)	30 (100%)
Grade 3+ TEAE	14 (44%)	19 (63%)	16 (50%)	16 (53%)
TRAE	19 (59%)	24 (80%)	27 (84%)	29 (97%)
Grade 3+ TRAE	5 (16%)	10 (33%)	7 (22%)	13 (43%)
Serious TRAE	3 (9%)	10 (33%)	8 (25%)	11 (37%)
Grade 5 serious TRAE	0	2 (7%)	1 (3%)	0
TRAE leading to discontinuation	2 (6%)	7 (23%)	5 (16%)	12 (40%)
Grade 1/2 TR-irAE leading to discontinuation	0 (0%)	2 (7%)	3 (10%)	2 (7%)
TR-irAE[1]	6 (19%)	20 (67%)	18 (56%)	22 (73%)
Grade 3+ TR-irAE	4 (13%)	9 (30%)	5 (16%)	11 (37%)
Infusion-related reactions[2]	4 (13%)	8 (27%)	3 (9%)	7 (23%)

- The most common TRAEs overall (≥15%) were skin and subcutaneous tissue disorders (50%) and endocrine disorders (26%)
- The most common TEAEs leading to discontinuation were skin and subcutaneous tissue disorders (6%) and respiratory, thoracic and mediastinal disorders (6%)
- Fatal serious TRAEs include immune-mediated pneumonitis (N=1), immune-mediated hepatitis (N=1) and immune-mediated myocarditis (N=1)

[1]Immune-related AEs are events of potential immunologic aetiology, including irAEs; irAEs are identified as any Grade 2+ AEs (or AEs of unknown grade) based on a prespecified search list of preferred terms using the most recent MedDRA version identified by a custom MedDRA query (CMQ) using GSK Terms of Interest codes; [2]infusion-related reactions are drug component–related AEs which occurred ≤1 day after drug component infusion and are identified based on a prespecified search list of preferred terms and most recent MedDRA version. AE, adverse event; irAE, immune-related AE; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event; TR, treatment-related; TRAE, treatment-related treatment-emergent adverse event.

Belrestotug + Dostarlimab Is Broadly Consistent with Known Safety Profile of Checkpoint Inhibitor Combinations

Most common TR-irAE were skin and subcutaneous tissue disorders

Event, n (%)	Dostarlimab N=32	A: Belrestotug 100 mg + dostarlimab (N=30)	B: Belrestotug 400 mg + dostarlimab (N=32)	C: Belrestotug 1000 mg + dostarlimab (N=30)
TR-irAE[1] by preferred terms (≥10% incidence in any cohort[2]), Grade 2+ Grade 3+				
Immune-mediated dermatitis	0 0	5 (17%) 1 (3%)	0 0	6 (20%) 3 (10%)
Pruritus	0 0	3 (10%) 0	5 (16%) 0	4 (13%) 0
Rash	0 0	2 (7%) 0	4 (13%) 0	2 (7%) 1 (3%)
Immune-mediated hypothyroidism	1 (3%) 0	1 (3%) 0	3 (9%) 0	4 (13%) 0
ALT increase	1 (3%) 1 (3%)	3 (10%) 2 (7%)	0 0	1 (3%) 1 (3%)
Immune-mediated lung disease	0 0	1 (3%) 0	1 (3%) 0	3 (10%) 1 (3%)
Immune-mediated myocarditis	0 0	1 (3%) 1 (3%)	0 0	3 (10%) 1 (3%)

- The majority of Grade 2+ irAEs were skin and subcutaneous tissue disorders across all combination cohorts and were considered generally manageable with steroids (topical or oral). Adaptions to skin toxicity management are ongoing.
- Immune-mediated lung disease and myocarditis were more frequent in the belrestotug 1000 mg + dostarlimab cohort

[1]Immune-related AEs are events of potential immunologic aetiology, including irAEs; irAEs are identified as any Grade 2+ AEs (or AEs of unknown grade) based on a prespecified search list of preferred terms using the most recent MedDRA version identified by a custom MedDRA query (CMQ) using GSK Terms of Interest codes; [2]infusion-related reactions are drug component–related AEs which occurred ≤1 day after drug component infusion and are identified based on a prespecified search list of preferred terms and most recent MedDRA version. AE, adverse event; irAE, immune-related AE; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event; TR, treatment-related; TRAE, treatment-related treatment-emergent adverse event.

Closing Remarks

Michel Detheux, PhD

Chief Executive Officer & President

GALAXIES Lung-301 - Phase 3 in 1L NSCLC

Key

Ⓡ Subjects Randomization

Study Design

Estimated Enrollment 1,000

Status	Enrolling
Masking	Double-blind
PDL1 Expression	≥50%
Lines of Therapy	No prior systemic therapy
Delivery	IV Infusion

Objectives	Evaluate belrestotug + dostarlimab safety, efficacy vs placebo + pembrolizumab
Primary Endpoint	PFS, OS
Secondary Endpoint	ORR, MRR, DOR

NSCLC, non-small cell lung cancer; PFS, progression free survival; OS, overall survival; ORR, overall response rate; MRR, molecular response rate; DOR, duration of response

Deep Responses with Generally Manageable Safety Profile Observed with Belrestotug + Dostarlimab

~60% cORR at every dose of belrestotug + dostarlimab vs ~28% for dostarlimab

>30% cORR difference observed at every dose of belrestotug + dostarlimab vs dostarlimab

Numerically Greater ctDNA Reduction Observed by belrestotug 400mg and 1000mg + dostarlimab cohorts vs dostarlimab

Generally Manageable IRAEs Belrestotug + dostarlimab safety profile broadly consistent with IO combinations

Next Steps

GALAXIES Lung-201:
Longer-term follow-up data in 2025

GALAXIES Lung-301:
Enrolling

Upcoming TIGIT 2024 + 2025 Catalyst Calendar

2024

✓ **1L NSCLC**
(Phase 2 GALAXIES LUNG-201 - ORR)

2025

1L NSCLC
(Phase 2 GALAXIES LUNG-201)

1L HNSCC
(Phase 2 TIG-006 + GALAXIES H&N-202 data)

Funded Through Significant Milestones

As of June 30, 2024

~$714M

Pro forma cash, cash equivalents and short-term investments

Runway through 2027

*Pro forma cash, cash equivalents and short-term investments
NSCLC, non-small cell lung cancer; HNSCC, head and neck squamous cell carcinoma; ENT1, Equilibrative Nucleoside Transporter 1; MoA, Mechanism of Action

iTEOS THERAPEUTICS

Cancer Immunotherapies by *design*™

Nasdaq: ITOS September 2024