

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): January 10, 2024

**iTeos Therapeutics, Inc.**

(Exact name of Registrant as Specified in Its Charter)

Delaware  
(State or Other Jurisdiction  
of Incorporation)

001-39401  
(Commission File Number)

84-3365066  
(IRS Employer  
Identification No.)

321 Arsenal Street  
Watertown, Massachusetts  
(Address of Principal Executive Offices)

02472  
(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 January 10, 2024, Michel Detheux, Ph.D., President and Chief Executive Officer of iTeos Therapeutics, Inc., will present at the 42nd Annual J.P. Morgan Healthcare Conference (the "Conference"). The slides that will be presented by Dr. Detheux at the Conference are furnished with this report as Exhibit 99.1, which is incorporated herein by reference.

*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.**

<u>Exhibit No.</u>	<u>Description</u>
99.1	<a href="#">iTeos Therapeutics, Inc. Presentation at the 42nd Annual J.P. Morgan Healthcare Conference dated January 10, 2024</a>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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**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: January 10, 2024

By: /s/ Michel Detheux  
Michel Detheux, Ph.D.  
President and Chief Executive Officer

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# Cancer Immunotherapies *by design*<sup>™</sup>

Nasdaq: ITOS      January 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 our product candidates and combinations, including the potential of belrestotug to be the highest quality TIGIT in the field, the potential of EOS-984's mechanism to have profound effects as a monotherapy or in combinations, and the potential of inupadenant to enhance chemotherapy therapeutic response; the expectation that 2024 will be a defining year for iTeos; our clinical and data generation plans for 2024, including initiating a TIGIT Phase 3 registrational study, having clinical data from GALAXIES Lung-201 and TIG-006 HNSCC, having clinical data from the dose escalation portion of A2A-005 in late 2024, presenting preclinical mechanism of action data from EOS-984 in the second quarter of 2024, and having topline data from the Phase 1 dose escalation trial in advanced malignancies in late 2024; our goal to gain commercial approval for belrestotug in 1L NSCLC and branch into earlier lines and potentially to a variety of IO amenable tumors; the potential of our biomarker for TIGIT in identifying indications to target and subpopulations; our market opportunities and number of patients potentially eligible for our product candidates; the potential benefits of our collaboration with GSK and the expectation that 2024 will be a year of significant momentum for this collaboration; and our expected cash runway through 2026, which contemplates the launch of multiple TIGIT Phase 3 trials.

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; the data for our product candidates may not be sufficient to support regulatory approval; 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; the expected benefits and opportunities related to the agreement between iTeos and GSK may not be realized or may take longer to realize than expected 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; 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' Quarterly Report on Form 10-Q for the nine months ended September 30, 2023 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 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 considerable reliance on the forward-looking statements contained in this press release. iTeos does not undertake any obligation to publicly update its forward-looking statements based on events or circumstances after the date hereof.

# 2024

## A Defining Year for iTeos

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### Promising TIGIT:PD-1 Doublet

**1**

**Two** Data Readouts Anticipated in 2024

### Unlocking Adenosine Pathway

**2**

**Two** Data Readouts Anticipated in 2024

### Funded Through 2026

**3**

**\$645M** in cash as of 3Q23

# Deep Pipeline with Four Clinical Readouts in 2024

Innovative molecules and compelling combinations



	Preclinical	Phase 1	Phase 2	Phase 3	Status
<b>Belrestotug: IgG1 antibody targeting TIGIT</b>					
+ dostarlimab   1L NSCLC PDL1 <sup>high</sup>					Planned Study
+ dostarlimab   1L NSCLC PDL1 <sup>high</sup> GALAXIES Lung-201					Data Anticipated 2024
+ dostarlimab   1L HNSCC PDL1 <sup>high/low</sup> TIG-006					Data Anticipated 2024
+ dostarlimab + CD96   1L HNSCC PDL1 <sup>high</sup> GALAXIES H&N-202					Enrolling
+ dostarlimab + chemotherapy   1L mNSCLC TIG-006					Enrolling
+ dostarlimab + CD96   Advanced Malignancies NCT03739710					Enrollment Complete
+ dostarlimab + PVRIG   Advanced Malignancies NCT05277051					Enrolling
<b>Inupadenant: Small molecule targeting A<sub>2A</sub> receptor</b>					
+ chemotherapy   Post-IO Chemo-naïve NSCLC A2A-005					Data Anticipated Late 2024
<b>EOS-984: Small molecule targeting ENT1</b>					
Monotherapy   Advanced Malignancies					Data Anticipated 2024

ENT1, Equilibrative Nucleoside Transporter 1; (m)NSCLC, (metastatic) non-small cell lung cancer; HNSCC, head and neck squamous cell carcinoma

# Belrestotug

EOS-448 / GSK4428859A

iTeos and GSK are uniquely positioned to leverage the TIGIT/CD226 axis

We Hold An  
**Advantageous**  
**Field Position**

*Significant momentum in 2023*



## We Believe Our TIGIT:PD-1 Doublet Is Differentiating In Key Areas

Proven quality target engagement with TIGIT and FcγR

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TIGIT monotherapy activity

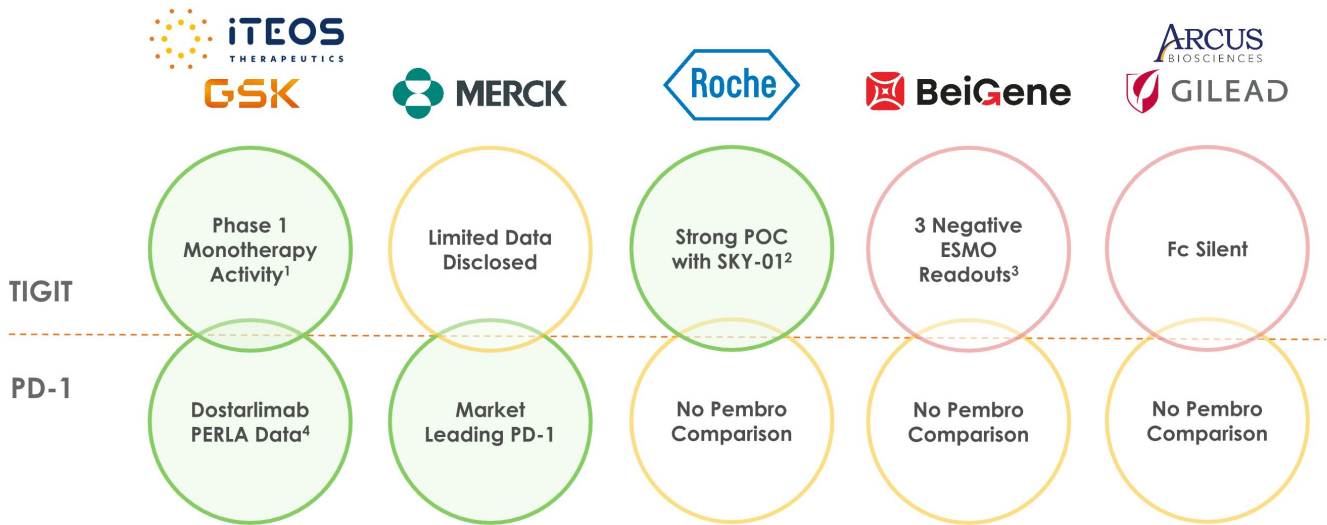
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Pembrolizumab comparison



# The Need for a Transformative TIGIT:PD-1 Doublet

*Belrestotug + dostarlimab represent differentiated, high-quality therapies*



1. iTeos AACR 2021  
 2. Genentech Phase 3 Skyscraper-01 Study - August 22, 2023 Release  
 3. ESMO 2023 - AdvanTIG-203, AdvanTIG-206, AdvanTIG-202  
 4. ESMO 2023 - Phase 2 GSK-sponsored PERLA study in 1L NSCLC

POC, proof of concept; Pembro, pembrolizumab

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

Unique Epitope Binding

## High Affinity + Potency

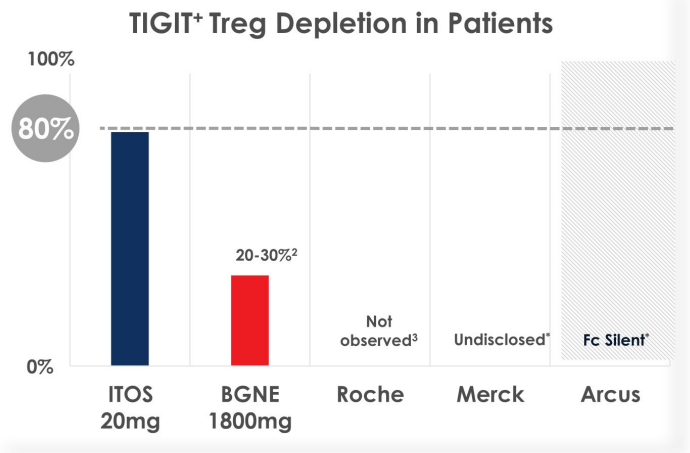
First and only TIGIT with proven

## Treg depletion at all doses<sup>1</sup>

Only TIGIT to Demonstrate Phase 1

## Monotherapy Activity<sup>1</sup>

1. iTeos AACR 2021
2. doi: 10.1136/jitc-2022-SITC2022.0768
3. Piper Sandler Virtual BioInsights KOL Day: Expert Call on Next Generation Cancer Immunotherapy – June 2020



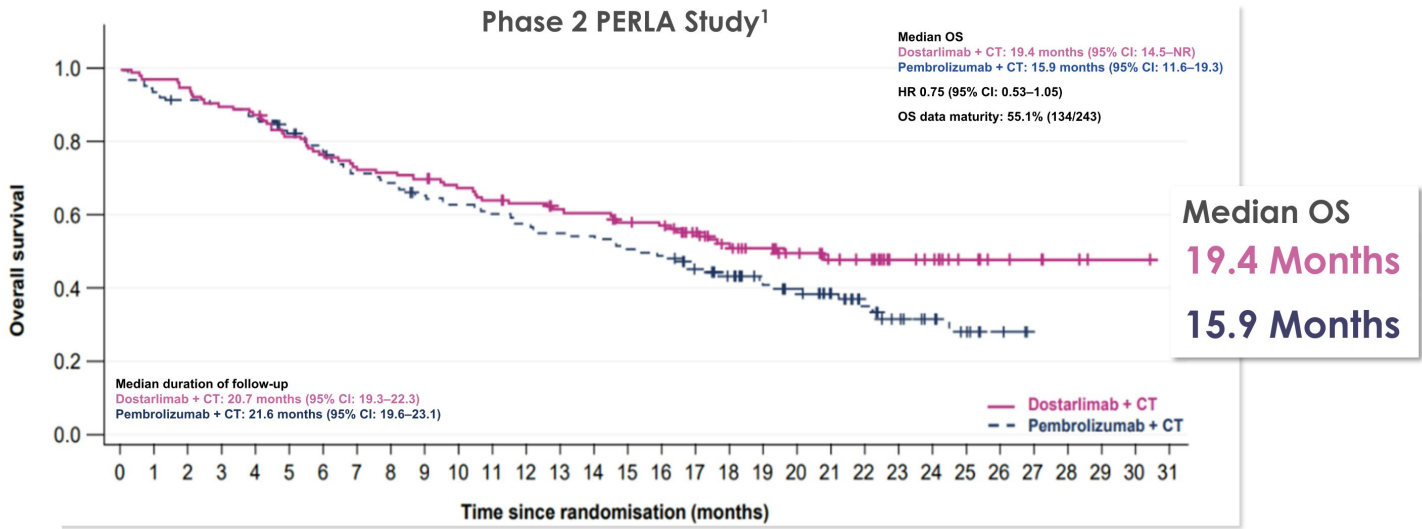
\*Merck vibostolimab has yet to publicly show Treg depletion data; Arcus' domvanalimab is an Fc silent TIGIT and not capable of Treg depletion

<sup>3</sup> Ira Melman, Vice President, Cancer Immunology at Genentech: "We would have loved to see Treg depletion...I know that [TIGIT] is also present in fairly high abundance on regulatory T cells but neither in the mouse models nor in cancer patients can we really find much or certainly dramatic evidence that Treg compartment is diminished as a consequence of TIGIT exposure."



# PERLA: Dostarlimab Is A Quality Anti-PD-1 Backbone

Positive numerical OS trend in 1L NSCLC favoring dostarlimab + CT vs. pembrolizumab + CT

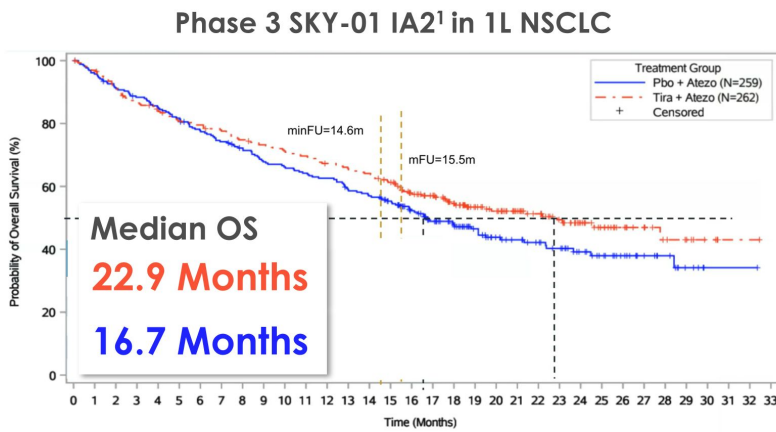


<sup>1</sup>Phase 2 GSK-sponsored PERLA study in 1L NSCLC. Peters S, et al. Annals of Oncology (2023) 34 (suppl\_2): S1254-S1335. 10.1016/annonc/annonc1358. NB: Safety profiles in the secondary analysis of OS were similar and consistent with those previously reported in the primary analysis for the PERLA trial.

# SKY-01: Meaningful Separation of Curves Validates TIGIT



Quality of components and clinical trial design leave room for improvement

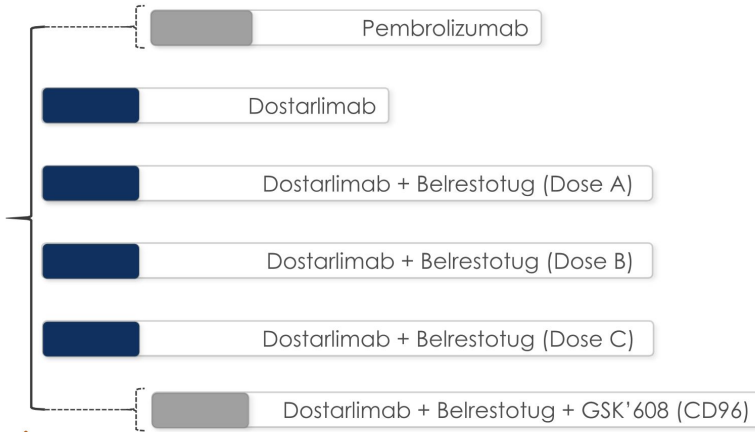


## Key Insights

- Validated TIGIT as a target** with mOS extended by ~6 months
- Robust study design** could provide meaningful efficacy and safety evaluation
- Incorporation of pembrolizumab** as SoC control arm

# GALAXIES Lung-201 - Phase 2 in 1L NSCLC

The largest TIGIT Phase 2 in 1L NSCLC



**Estimated Enrollment**

300

## Study Design

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

[iteostherapeutics.com](http://iteostherapeutics.com)

12

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

# 1L NSCLC: Building A Meaningful Position

*Evolving competitive landscape favoring a high-quality TIGIT:PD-1 doublet*



**Strong scientific rationale** with high levels of TIGIT<sup>+</sup> Tregs, high infiltration of T cells, and highly amenable to IO therapies

**The right Phase 3 strategy** with right dose, right combination, right trial design, and right commercial approach

**1L NSCLC launch point** and clinical POC enables future exploration of other NSCLC settings and indications beyond lung



Source: Kantar, internal iTeos analysis

# GALAXIES H&N-202: Phase 2 in 1L HNSCC



## Study Design

Estimated Enrollment

360

<b>Status</b>	Enrolling	<b>Objectives</b>	Evaluate antitumor activity, safety of Dostarlimab + novel IOs
<b>Masking</b>	Open label	<b>Primary Endpoint</b>	ORR
<b>PDL1 Expression</b>	PDL1+	<b>Secondary Endpoint</b>	PFS, OS, DOR
<b>Lines of Therapy</b>	No prior systemic therapy	<b>Clinical Trials Listing</b>	NCT06062420
<b>Delivery</b>	IV Infusion		

[iteostherapeutics.com](http://iteostherapeutics.com)

HNSCC, head and neck squamous cell carcinoma; ORR, overall response rate; PFS, progression free survival; OS, overall survival; DOR, duration of response



**Study Design**

**Estimated Enrollment**

80

<b>Status</b>	Enrolling	<b>Objectives</b>	Evaluate Belrestotug + Dostarlimab in two CPS populations
<b>Masking</b>	Open label	<b>Primary Endpoint</b>	ORR
<b>PDL1 Expression</b>	PDL1+	<b>Secondary Endpoint</b>	PFS, OS, DOR
<b>Lines of Therapy</b>	No prior systemic therapy	<b>Clinical Trials Listing</b>	NCT05060432
<b>Delivery</b>	IV Infusion		

[iteotherapeutics.com](http://iteotherapeutics.com)

# 1L HNSCC: Potential First-to-Market Opportunity

*Under-served population with strong biological rationale seeking advances*



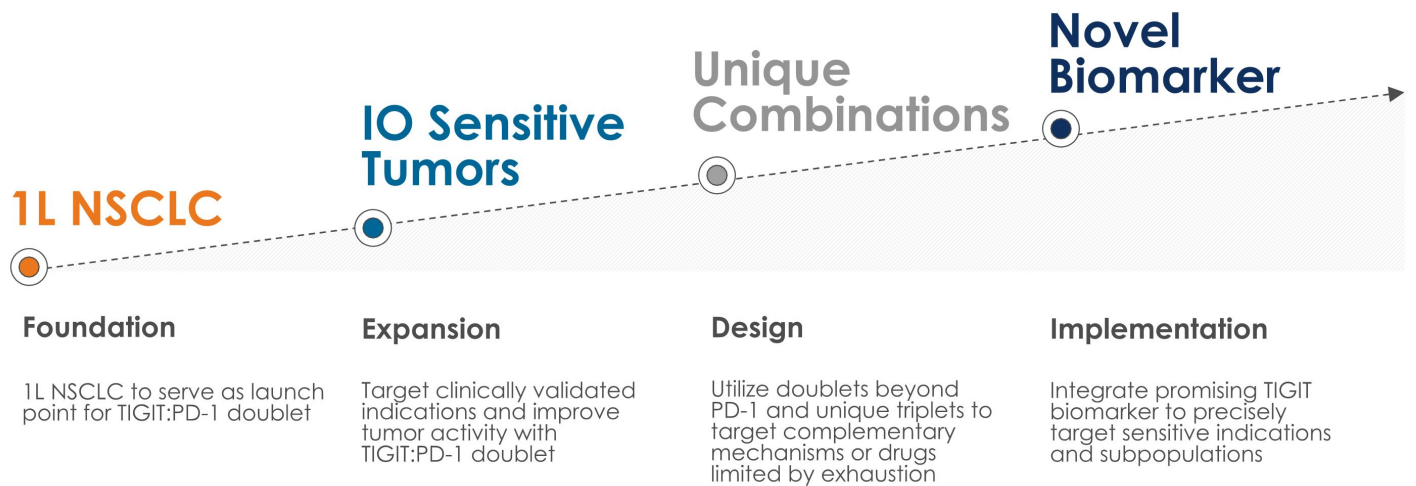
**Strong scientific rationale** with high levels of TIGIT<sup>+</sup> Tregs, high infiltration of T cells and the indication being amenable to PD-1 therapy

**Significant market opportunity** due to no ongoing Phase 3 studies, potential to be first-to-market, and the opportunity to expand to the locally advanced setting



Source: Kantar, internal iTeos analysis

# Belrestotug + Dostarlimab Are Uniquely Positioned to Fully Exploit TIGIT Pathway





# The Right Deal & The Right Partner

Data-driven approach to unlock potential of high-quality regimens



## Success Factors



Quality TIGIT



Proven PD-1



Right Partner



Strategic Approach



### Payments

**\$625M** upfront,  
up to **\$1.45B** milestones



### Territories

**US**: co-commercialization  
and **50/50 profit share**

**Ex-US**: double digit royalties  
up to **20%**



### Developmental expenses

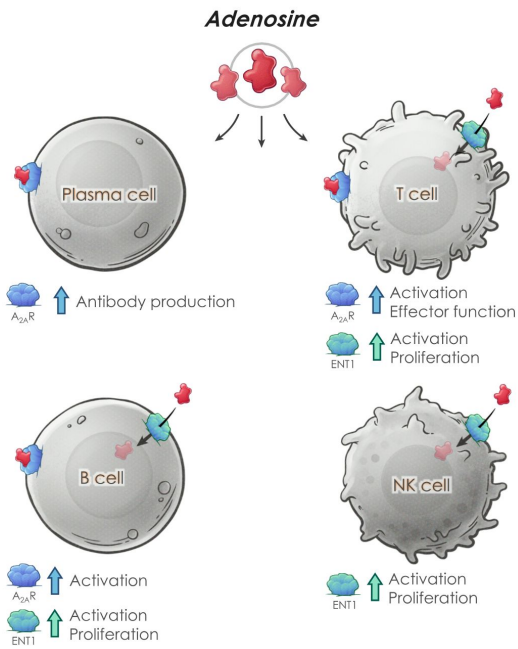
**40%** iTeos / **60%** GSK

PFS, progression free survival; OS, overall survival; dMMR, mismatch repair deficient

# Adenosine Pathway

Unlocking one of the most promising targets responsible for immunosuppression

# Addressing The Critical Adenosine Pathway Issue: Adenosine Inhibits Immune Cell Activity + Proliferation



## Inupadenant: Best-in-Class Approach

- Targets A<sub>2A</sub>R, restoring immune cell activity, specifically plasma cell antibody production
- First and only A<sub>2A</sub>R antagonist to maintain activity at high adenosine concentrations

## EOS-984: First-in-Class Approach

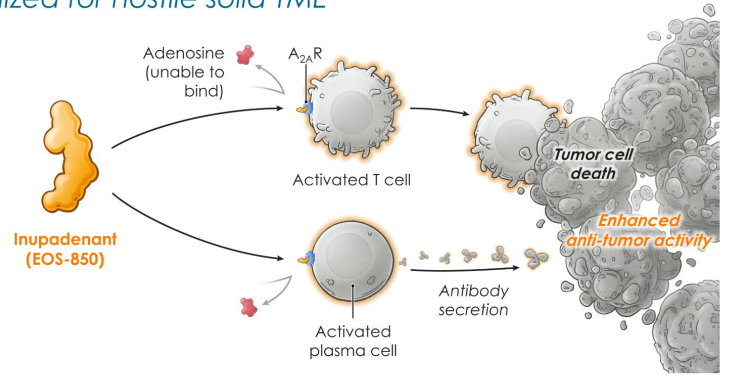
- Targets ENT1, a major adenosine transporter involved in T cell expansion, effector function, and survival
- Potential to restore T cell proliferation in hostile TME

# Inupadenant: A Class of Its Own

Best-in-class, highly selective  $A_{2A}R$  antagonist optimized for hostile solid TME

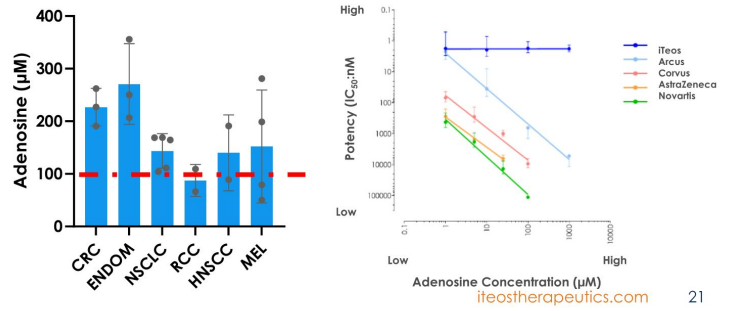
## Targeting $A_{2A}R$

- $A_{2A}R$  activation by adenosine suppresses immune cell responses, inhibiting anti-tumor response
- Inupadenant targets  $A_{2A}R$ , the final endpoint of the adenosine production pathway, circumventing the multiple ways adenosine is created



## The Insurmountable Profile of Inupadenant

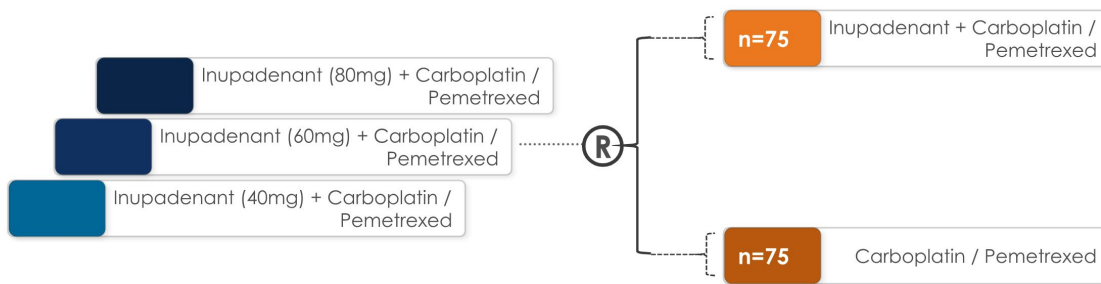
- First company to demonstrate TME adenosine concentration is supraphysiological and varies depending on indication
- First and only  $A_{2A}R$  antagonist to maintain activity at high adenosine concentrations



TME, tumor microenvironment

## Key

**R** Subjects Randomization



## Study Design

**Estimated Enrollment**

192

<b>Status</b>	Enrolling	<b>Objectives</b>	Evaluate Clinical Benefit of Inupadenant + Chemotherapy
<b>Masking</b>	Double Blind	<b>Primary Endpoint</b>	ORR
<b>PDL1 Expression</b>	PDL1+ (all %)	<b>Secondary Endpoint</b>	PFS, OS, DOR
<b>Lines of Therapy</b>	1; PD-1 Inhibitors	<b>Clinical Trials Listing</b>	NCT05403385
<b>Delivery</b>	Oral		

# Inupadenant Counteracts Chemotherapy's Key Downfall



2L NSCLC is an under-served population with strong biological rationale seeking advances

**Chemotherapy increases adenosine levels via cell death**, hindering the immune system and plasma cell activity

**Inupadenant maintains potency + function at high adenosine levels**, potentially enhancing chemotherapy therapeutic response

Currently only clinical trial in 2L NSCLC platinum-naïve setting



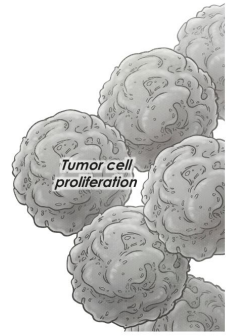
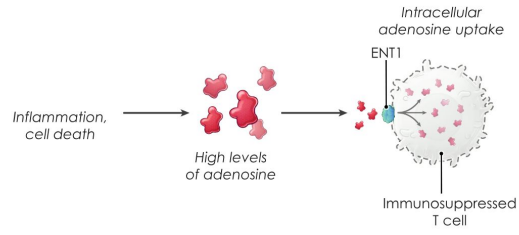
Source: Kantar, internal iTeos analysis

# EOS-984: Enhancing T Cell Proliferation in the Hostile TME

One of the most meaningful discoveries in the adenosine pathway

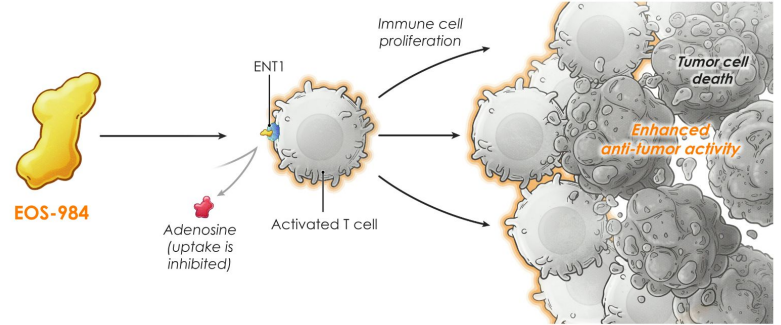
## The Role of ENT1

- Dominant transporter of adenosine on lymphocytes effecting:
  - T cell metabolism
  - T cell effector function
  - T cell expansion
  - T cell survival



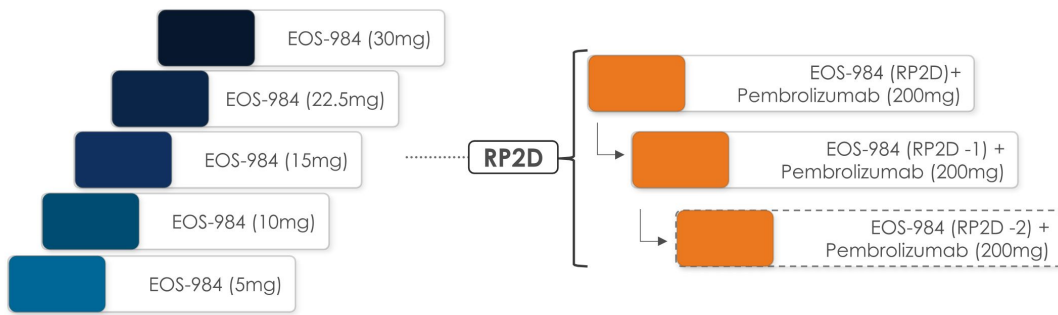
## The Opportunity to Revive T Cell Proliferation

- First company to understand how adenosine transports into T cells and inhibits proliferation
- EOS-984 offers large combination opportunity broadly across cancer therapies



# EOS-984: Phase 1 in Advanced Solid Tumors

Evaluation of target engagement and impact on T cells in TME



## Study Design

<b>Status</b>	Enrolling	<b>Objectives</b>	Evaluate Safety/Tolerability of EOS-984 as a Monotherapy and in Combination with Pembrolizumab
<b>Masking</b>	Open Label	<b>Primary Endpoint</b>	Safety/Tolerability, PK/PD
<b>PDL1 Expression</b>	PDL1+ (all %)	<b>Secondary Endpoint</b>	ORR, PFS, OS, DOR
<b>Lines of Therapy</b>	All-comers		
<b>Delivery</b>	Oral		



## TIGIT

### 1L NSCLC

(Phase 2 GALAXIES LUNG-201)

.....

### 1L HNSCC

(Phase 2 TIG-006)

## Adenosine Pathway

### A<sub>2A</sub>R - 2L NSCLC

(Phase 2 A2A-005)

.....

### ENT1 - MOA

(EOS-984 Preclinical)

.....

### ENT1 - Advanced Malignancies

(EOS-984 Phase 1)

## Funded Through Significant Milestones

As of 3Q23

# \$645M

In cash, cash equivalents and investments

## Runway through 2026



# Cancer Immunotherapies *by design*<sup>™</sup>

Nasdaq: ITOS    January 2024