

Telisotuzumab Adizutecan and PD-1 Inhibitor in Untreated Advanced Nonsquamous Non-Small Cell Lung Cancer: AndroMETa-Lung-536, a Phase 1b/2 Study

Hidehito Horinouchi,¹ Kristof Cuppens,^{2,3} D. Ross Camidge,⁴ Shun Lu,⁵ Shirish Gadgeel,⁶ Jonathan Goldman,⁷ Nicolas Girard,⁸ Pin Li,⁹ Tony Navas,⁹ Raluca Predoiu,⁹ Theodore S. Jennaro,⁹ Han Coburn,⁹ Xi Chen,⁹ Elvire Pons-Tostivint¹⁰

¹National Cancer Center Hospital, Tokyo, Japan; ²Department of Pulmonology and Thoracic Oncology, Jessa Hospital, Hasselt, Belgium; ³Faculty of Medicine and Life Sciences LCRC, UHasselt, Diepenbeek, Belgium; ⁴University of Colorado Cancer Center, Aurora, CO, USA; ⁵Shanghai Lung Cancer Center, Shanghai Chest Hospital, School of Medicine, Shanghai Jiao Tong University, Shanghai, China; ⁶Emory University School of Medicine, Winship Cancer Institute of Emory University, Atlanta, GA, USA; ⁷David Geffen School of Medicine at UCLA, Los Angeles, CA, USA; ⁸Département d'Oncologie Médicale, Institut Curie, Paris, France; ⁹AbbVie Inc., North Chicago, Illinois, USA; ¹⁰Centre Hospitalier Universitaire Nantes, Nantes University, Nantes, France

OBJECTIVE

To evaluate safety, efficacy, and optimal dose of telisotuzumab adizutecan (ABBV-400, Temab-A) in combination with a checkpoint inhibitor in patients with locally advanced/metastatic nonsquamous non-small cell lung cancer (NSCLC) with no prior treatment for advanced disease and no actionable genomic alterations

TRIAL DESIGN

Phase 1b/2 (NCT06772623)

Open-label, dose escalation/dose optimization

Global, multicenter

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AbbVie and authors thank all the trial investigators and the patients who participated in this clinical trial.

AbbVie funded this study and participated in the trial design, research, analysis, data collection, interpretation of data, and the review and approval of the publication. All authors had access to relevant data and participated in the drafting, review, and approval of this publication. No honoraria or payments were made for authorship. Medical writing support was provided by Marianne Pons, PhD and Phillip Giannopoulos, PhD, CMPPP of Bio Connections, LLC, and funded by AbbVie.

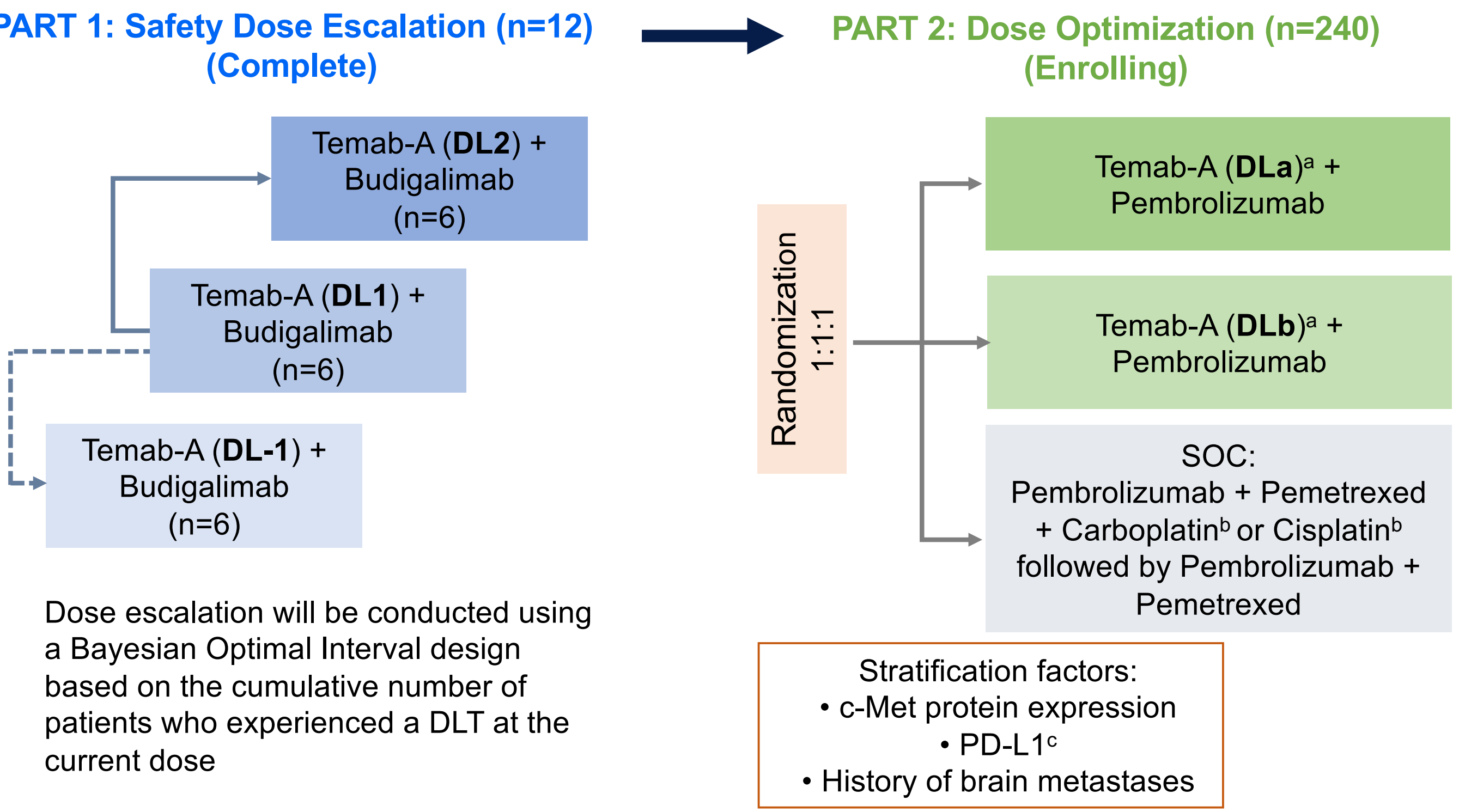
Financial arrangements of the authors with companies whose products may be related to the present report are listed as declared by the authors: **HH**: research funding (past 36 months) from AbbVie, AstraZeneca, BMS, Chugai/Roche, Daiichi Sankyo, Janssen, Natera, and ONO; honoraria for lectures, presentations, speakers' bureau, manuscript writing or educational events from AbbVie, AstraZeneca, Amgen, Bristol Myers Squibb, Chugai/Roche, MSD, and ONO; DSMB/Advisory Board for AbbVie, AstraZeneca, Bristol Myers Squibb, Chugai/Roche and ONO; **KC**: Advisory Boards for AbbVie, Amgen, AstraZeneca, Bristol-Myers Squibb, Daiichi Sankyo, Hoffman-La Roche, Iteos Therapeutics, Janssen, Merck Sharp & Dohme, and Pierre Fabre Oncology; Invited Speaker for AbbVie, AstraZeneca, BristolMyersSquibb, Hoffmann-La Roche, and Merck Sharp & Dohme; Expert Testimony for AstraZeneca and Merck Sharp & Dohme; **DRC**: ad hoc consulting for AbbVie; **SL**: research support from AbbVie, Astellas Pharma, AstraZeneca, Bristol Myers Squibb, MSD, Heng Rui, Beone, Hansoh Pharma, and Duality Biologics; speaker fees from AstraZeneca, Pfizer, MSD, BioNTech, Inventis Bio Co. Ltd., Shanghai Fosun Pharmaceutical (Group) Co., Ltd., Sincere Zaiming Pharmaceutical Co., Takeda and Duality Biologics; Independent Director of Board member of Inovvent Biologics, Inc; **SG**: consulting/advisory role for AstraZeneca, Bayer, Bristol Myers Squibb, Daiichi Sankyo, Eisai, Inc., Eisai, Genentech/Roche, Gilead Sciences, Johnson & Johnson/Janssen, Eli Lilly, Merck, MBrace, Pfizer, Regeneron, Summit Therapeutics, research funding (to institution) from AbbVie, Amgen, Arcus Biosciences, AmVent Biopharma, Astellas Pharma, AstraZeneca, Avistone Biotechnology, Bayer, D3 Bio, Daiichi Sankyo, Debiopharma Group, eFFECTOR Therapeutics, Genentech/Roche, Genmab, GRAIL, Helsinn Therapeutics, Incyte, InventisBio, Jovance Therapeutics, Jacobio, Janssen Oncology, Janux Therapeutics, Kymera, Merck, Mirati Therapeutics, Montelosa Therapeutics, Nimbus, Novita Pharmaceuticals, Numab, Nuvalent, Inc., Pfizer, Regeneron, Revolution Medicines, Tango Therapeutics, Turning Point Therapeutics, Versantia; other with AstraZeneca; **JB**: consulting/advisory role for AbbVie, AstraZeneca, Bristol Myers Squibb, Genentech, Lilly, Pfizer; research funding (to institution) AbbVie, AstraZeneca, Bristol Myers Squibb, Genentech, Lilly, Pfizer, and Spectrum; **NG**: research grants/support to institution from AbbVie, Amgen, AstraZeneca, BeOne, Boehringer Ingelheim, Bayer, BioNTech, Bristol Myers Squibb, Daiichi Sankyo, Gilead, Johnson & Johnson, Lilly, Sivan, Taiho; consultant for AbbVie, Accord, Amgen, AstraZeneca, BeOne, Bristol-Myers-Squibb, Daiichi Sankyo, Ipsen, Johnson & Johnson, Lilly, Merck Sharp & Dohme, Natera, Natera, Pfizer, Pharmamar, Pierre Fabre, Regeneron, and Summit; Speaker for AbbVie, Amgen, AstraZeneca, BeOne, Bristol Myers Squibb, Daiichi Sankyo, Johnson & Johnson, Merck Sharp & Dohme, Novocure; hospitality capacity for Bristol Myers Squibb, Johnson & Johnson, and Pierre Fabre; **PL**, **TN**, **RP**, **TJ**, **GM-T**, **XC**: employed by AbbVie and may own AbbVie stock or options; **EP-T**: Advisory Board/Consultant for AstraZeneca, Amgen, Bristol Myers Squibb, Daiichi Sankyo, Johnson & Johnson, MSD, Roche, and Sanofi.

BACKGROUND

- Increased expression of c-Met (also known as MET protein) is commonly observed in solid tumors including in patients with epidermal growth factor receptor wild type (*EGFR*^{WT}) nonsquamous NSCLC, and has been linked to worse clinical outcomes¹⁻³
- Addition of checkpoint inhibitors (ie, pembrolizumab) to frontline chemotherapy has improved outcomes in patients with untreated nonsquamous NSCLC; yet durable disease control remains elusive⁴
- Temab-A is an antibody-drug conjugate comprising the c-Met targeting antibody conjugated to a potent topoisomerase 1 inhibitor payload^{5,6}
- Budigalimab is an investigational programmed cell death receptor 1 (PD-1) inhibitor with a mechanism of action similar to the approved pembrolizumab in these patients⁷
- Preliminary findings from the first-in-human Phase 1 study indicated encouraging antitumor activity (cORR: 44%) and a manageable safety profile in heavily pretreated patients with advanced/metastatic *EGFR*^{WT} NSCLC⁶
- In this study, Temab-A in combination with a PD-1 inhibitor will be investigated for untreated, advanced *EGFR*^{WT} nonsquamous NSCLC

STUDY SCHEMA

- This is an open-label, global, dose escalation (Part 1)/dose optimization (Part 2), Phase 1b/2 study enrolling adult patients (N~252) with locally advanced/metastatic *EGFR*^{WT} nonsquamous NSCLC who did not receive any prior treatment for advanced disease and do not have any actionable genomic alterations
- The **primary objectives** are:
 - To evaluate the safety and tolerability of Temab-A in combination with budigalimab (Part 1) or pembrolizumab (Part 2)
 - To evaluate the efficacy and RP3D of Temab-A in combination with pembrolizumab



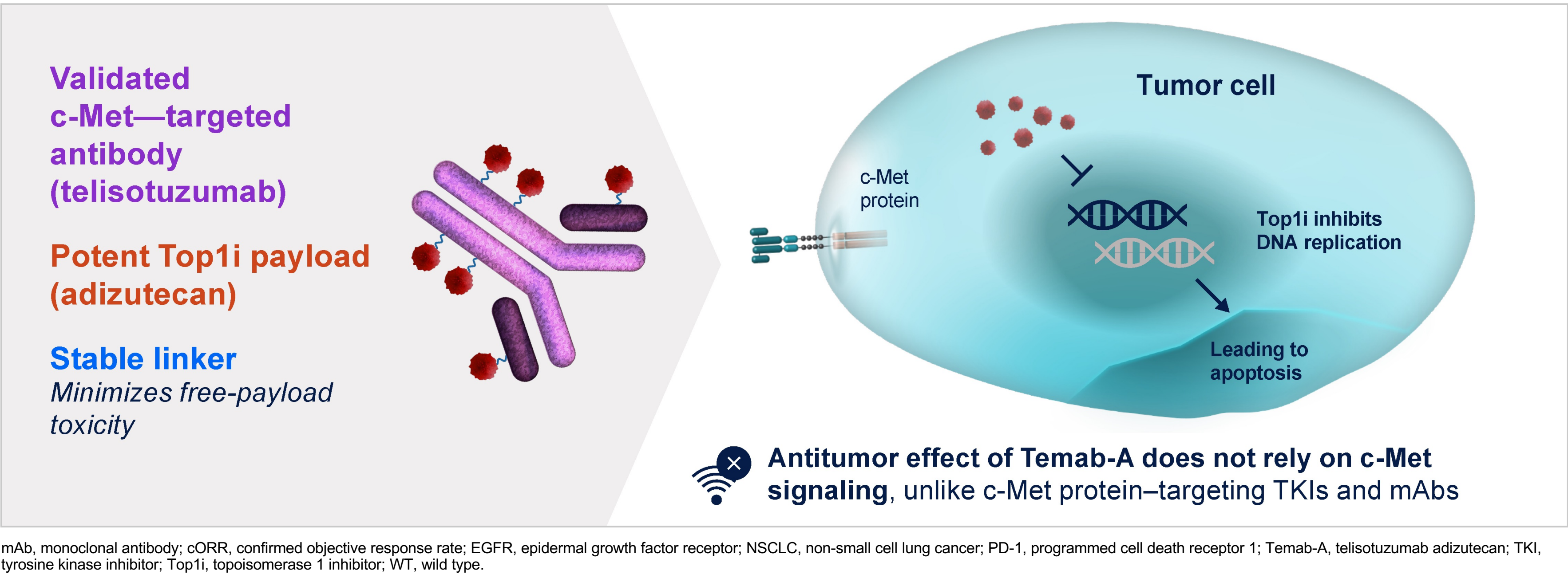
^aSelected doses based on Part 1. ^bInvestigator's choice. ^cNatural distribution or prevalence. DL, dose level; DLT, dose-limiting toxicity; EGFR, epidermal growth factor receptor; NSCLC, non-small cell lung cancer; PD-L1, programmed death-ligand 1; RP3D, recommended Phase 3 dose; SOC, standard of care; Temab-A, telisotuzumab adizutecan.

KEY ELIGIBILITY CRITERIA

PARTS 1 AND 2	
✓ Age ≥18 years ✓ ECOG PS 0–1 ✓ Histologically confirmed locally advanced/metastatic <i>EGFR</i>^{WT} nonsquamous NSCLC (Stage IIIB/IV) ✓ Measurable disease per RECIST v1.1 ✓ Documented PD-L1 status by approved local assay ✓ Documented <i>EGFR</i>^{WT} status per local testing ✗ No actionable genomic alterations (Part 2 only)	
PART 1	PART 2
✓ Up to 1 prior line of systemic therapy allowed for advanced/metastatic disease	✓ Evaluable c-Met IHC by central lab for stratification, not selection ✓ No prior systemic therapy for advanced/metastatic disease
History of brain metastases allowed (no active CNS disease prior to enrollment)	

CNS, central nervous system; ECOG PS, Eastern Cooperative Oncology Group performance status; EGFR, epidermal growth factor receptor; IHC, immunohistochemistry; NSCLC, non-small cell lung cancer, PD-L1, programmed death-ligand 1; RECIST, Response Evaluation Criteria in Solid Tumors; WT, wild type.

Temab-A Mechanism of Action



mAb, monoclonal antibody; cORR, confirmed objective response rate; EGFR, epidermal growth factor receptor; NSCLC, non-small cell lung cancer; PD-1, programmed cell death receptor 1; Temab-A, telisotuzumab adizutecan; TKI, tyrosine kinase inhibitor; Top1i, topoisomerase 1 inhibitor; WT, wild type.

STUDY ENDPOINTS

Primary efficacy endpoints	OR by BICR (Part 2)
Secondary efficacy endpoints	- PFS, DOR, and DC by BICR - OS - OR, PFS, OS, DOR, and DC by PD-L1 and c-Met expression and history of brain metastases
Safety endpoints	- Adverse events - Treatment discontinuation or dose modifications due to AEs - Dose-limiting toxicities (Part 1)
Pharmacokinetic endpoints	C_{max}, t_{max}, t_{1/2} and AUC
Exploratory endpoints	- Biomarker analyses (tissue NGS/RNaseq and ctDNA NGS/molecular response, PD-L1 IHC, <i>MET</i> amp) - Intracranial OR, PFS, and DOR by BICR - Patient reported outcomes

All responses per RECIST v1.1. AE, adverse event; amp, amplified; AUC, area under the curve (or plasma for payload) concentration versus time curve; BICR, blinded independent committee review; C_{max}, maximum observed serum (or plasma for payload) concentration; CR, complete response; ctDNA, circulating tumor DNA; DC, disease control; DOR, duration of response; IHC, immunohistochemistry; NGS, next generation sequencing; OR, overall response; ORR, objective response; OS, overall survival; PD-L1, programmed death-ligand 1; PFS, progression-free survival; PR, partial response; RECIST, Response Evaluation Criteria in Solid Tumors; RNaseq, RNA sequencing; RP3D, recommended Phase 3 dose; t_{1/2}, terminal elimination half-life; t_{max}, time to C_{max}.

ENROLLMENT IS ONGOING GLOBALLY

- Approximately 252 patients will be enrolled across 132 sites worldwide
- Enrollment began on March 6, 2025; **10 countries** are already enrolling, and **7 countries** are looking to begin enrollment

Study Sites

