# ZL-1310
# ENA 2024 Highlights

October 24, 2024

NASDAQ:ZLAB | HKEX:9688

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# Forward-Looking Statements

This presentation contains forward-looking statements about future expectations, plans, and prospects for Zai Lab, including, without limitation, statements regarding product candidates in our pipeline including ZL-1310 and related clinical trials and preclinical studies, the potential benefits and safety and efficacy of ZL-1310, and the potential treatment of SCLC and other DLL3-expressing tumors. These forward-looking statements may contain words such as “aim,” “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “forecast,” “goal,” “intend,” “may,” “plan,” “possible,” “potential,” “target,” “will,” “would,” and other similar expressions. Such statements constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements are not statements of historical fact or guarantees or assurances of future performance.

Forward-looking statements are based on our expectations and assumptions as of the date of this presentation and are subject to inherent uncertainties, risks, and changes in circumstances that may differ materially from those contemplated by the forward-looking statements. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including but not limited to (1) our ability to successfully commercialize and generate revenue from our approved products, (2) our ability to obtain funding for our operations and business initiatives, (3) the results of clinical and pre-clinical development of our product candidates, (4) the content and timing of decisions made by the relevant regulatory authorities regarding regulatory approvals of our product candidates, (5) risks related to doing business in China, and (6) other factors discussed in our most recent annual and quarterly reports and other reports we have filed with the U.S. Securities and Exchange Commission (SEC). We anticipate that subsequent events and developments will cause our expectations and assumptions to change, and we undertake no obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required by law. These forward-looking statements should not be relied upon as representing our views as of any date subsequent to the date of this presentation.

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# Agenda

**Alex Spira, MD, PhD, FACP, FASCO**

Co-Director, Virginia Cancer Specialists Research Institute

**Rafael Amado, MD**

President, Head of Global Research and Development, Zai Lab

- **ZL-1310 (DLL3 ADC) Highlights from ENA 2024**
- **Closing Remarks**
- **Q&A**

## Alex Spira, MD, PhD, FACP, FASCO

Co-Director, Virginia Cancer Specialists Research Institute

- Director, Thoracic and Phase I Program, Clinical Assistant Professor, Johns Hopkins
- Director of Clinical Research and CEO at NEXT Virginia
- Recognized as a Top Doctor in Northern Virginia Magazine and Washingtonian magazine
- Received the prestigious “Castle Connolly America’s Top Doctor” award in 2024
- MD, New York University School of Medicine, PhD, New York School of Arts and Sciences

**ZL-1310 (DLL3 ADC) Highlights from ENA 2024**

Closing Remarks

Q&A

# Disclosure Information

Dr. Alexander Spira is a part of the following advisory committees and has conducted the following contracted research:

| | |
|---|---|
| **Advisory Committees** | Amgen Inc, Array BioPharma Inc, a subsidiary of Pfizer Inc, AstraZeneca Pharmaceuticals LP, Black Diamond Therapeutics Inc, Blueprint Medicines, Bristol Myers Squibb, Daiichi Sankyo Inc, Gritstone bio, Incyte Corporation, Janssen Biotech Inc, Jazz Pharmaceuticals Inc, Lilly, Merck, Mersana Therapeutics Inc, Mirati Therapeutics Inc, Novartis, Regeneron Pharmaceuticals Inc, Sanofi, Takeda Pharmaceuticals USA Inc |
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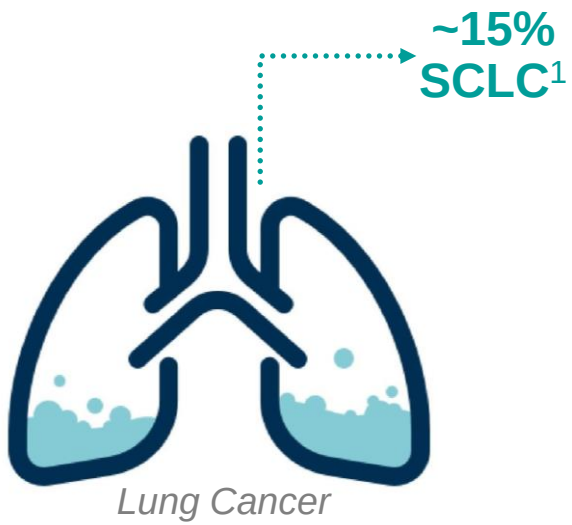
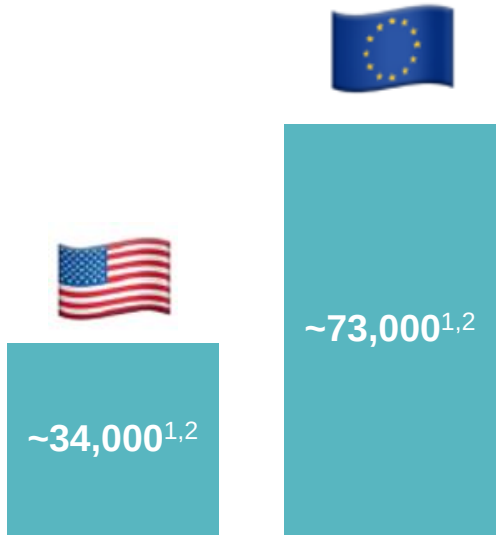
# SCLC – Highly Aggressive Disease with a Significant Unmet Need

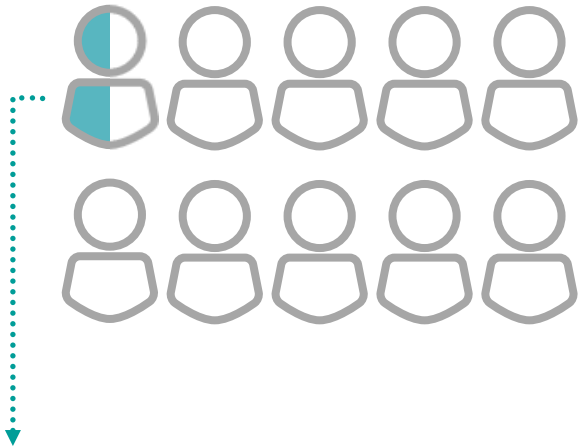
**SCLC** – An underserved high unmet medical need




Worldwide **~372,000** newly diagnosed patients with SCLC each year[1,2]




**High** aggressive disease associated with **poor** survival outcomes



- ✓ **2/3** diagnosed with extensive-stage[3]
- ✓ Limited treatment options in both the U.S. and EU
- ✓ **5-10%** overall survival rate at 5 years[4]

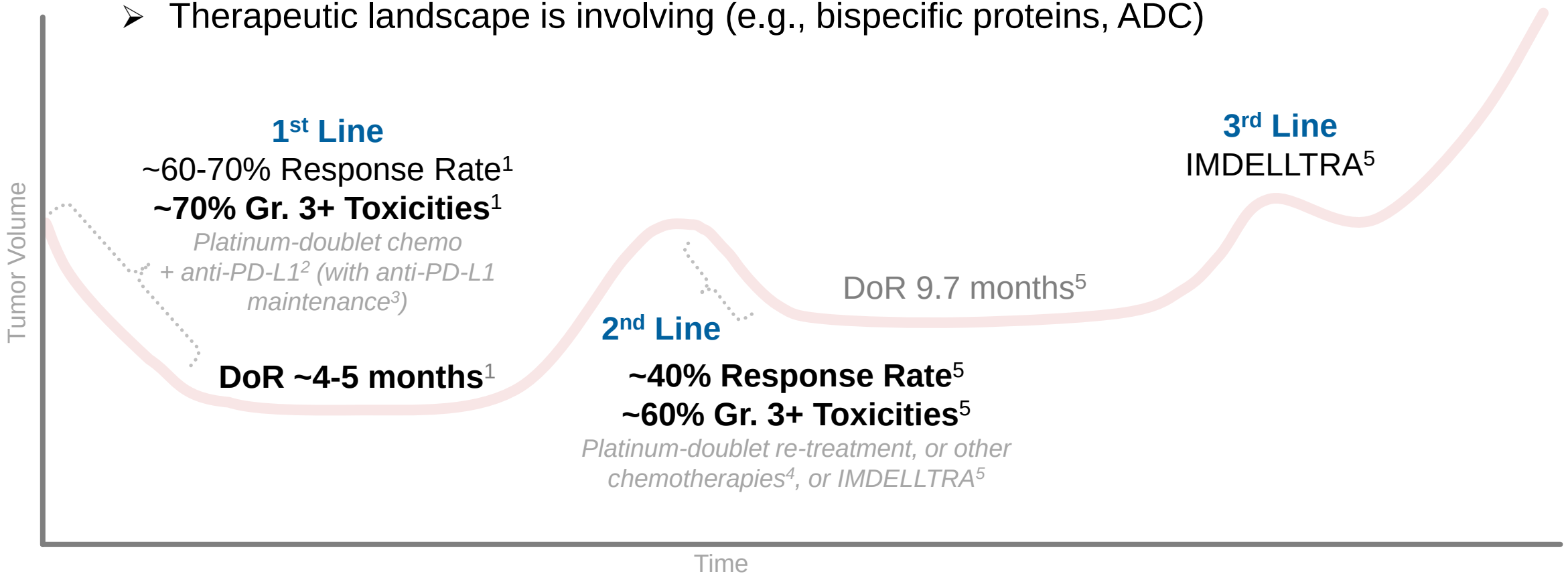
Abbreviation: Small cell lung cancer (SCLC).

Notes: (1) J Thorac Oncol. 2023 Jan;18(1):31-46; Lung Cancer Foundation of America. (2) WHO Globocan 2022. (3) Sabari JK, et al. Nat Rev Clin Oncol. 2017;14:549-561. (4) National Cancer Institute. www.cancer.gov. Accessed October 15, 2024.

# Patients with ES-SCLC are at Risk for Poor Efficacy and Safety Outcomes and Rapid Disease Progression

## Unmet Needs Remain with **Room for Improvement in Efficacy and Safety**

- Therapeutic landscape is involving (e.g., bispecific proteins, ADC)




Abbreviations: Antibody-Drug Conjugate (ADC), Duration of Response (DoR), Grade 3 or higher (Gr. 3+), extensive-stage small cell lung cancer (ES-SCLC).

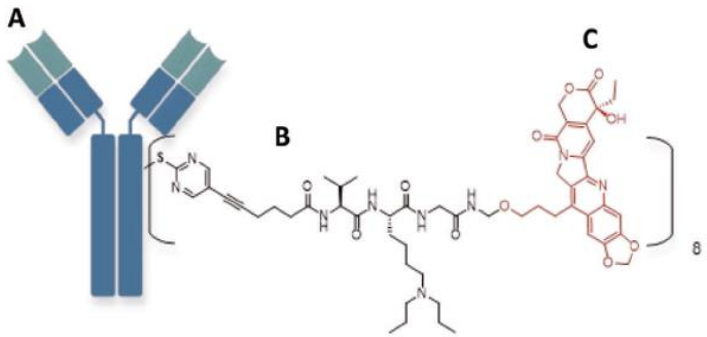
Sources: NCCN Guidelines: SCLC. Version 2.2025; UpToDate: Extensive-stage small-cell lung cancer: Initial management; Treatment of refractory and relapsed small cell lung cancer.

Notes: (1) Leora Horn et al. 2018 NEJM; Paz-Ares, Luis, et al. The Lancet 394.10212 (2019): 1929-1939. (2) Anti-PD-L1 (atezolizumab or durvalumab) + platinum + etoposide. (3) atezolizumab or durvalumab. (4) Platinum + etoposide re-treatment if progression in more than 6 months, or single-agent chemotherapy (lurbinectedin, topotecan, irinotecan) if progression in less than 6 months. (5) Ahn et al. N Engl J Med.2023; Sands et al. WCLC 2024; Amgen May 2024 Investor Presentation. IMDELLTRA is being evaluated in this setting. In May 2024, IMDELLTRA received FDA accelerated approval for the treatment of adult patients with ES-SCLC with disease progression on or after platinum-based chemotherapy. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

# ZL-1310: Novel Delta-Like Ligand 3 (DLL3) Targeting ADC

- DLL3 is a neuroendocrine-specific antigen that is a validated target and is highly expressed in SCLC, an indication with a high unmet medical need[1-3]
- ZL-1310 is a novel ADC that employs the TMALIN® (Tumor Microenvironment Activable LINker-payload) platform and targets DLL3 with an anti-DLL3 monoclonal antibody linked to a topoisomerase I inhibitor payload via a protease-cleavable linker[4]

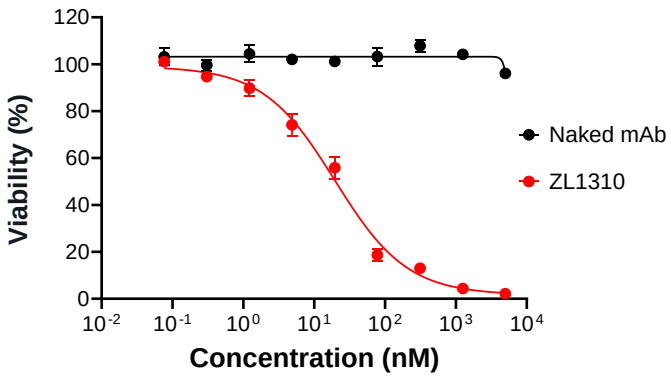
## Structure of ZL-1310[4]



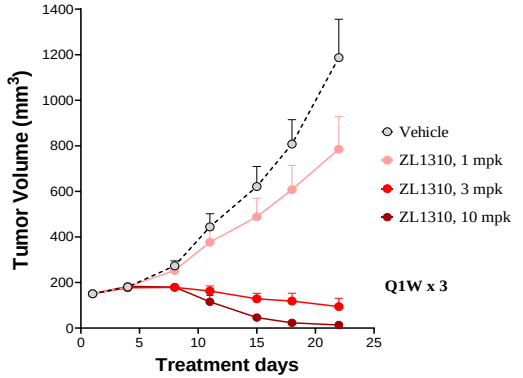

A: Humanized anti-DLL3 IgG1 mAb
B: Cleavable tripeptide-based linker
C: Camptothecin derivative payload, C24; DAR=8

## ZL-1310 Preclinical Activitiy[4]

ZL-1310-mediated cytotoxicity in DLL3+ NCI-H69 SCLC Cells




ZL-1310-mediated significant TGI in human SCLC LU5215 (DLL3low) PDX Model




DLL3: delta-like ligand 3; DAR: drug-to-antibody ratio Ig: immunoglobulin; mAb: monoclonal antibody; mpk: milligrams per kilograms; nM: nanomolar; PDX: patient-derived xenograft; Q1W: once weekly; SCLC: small cell lung cancer; TGI: tumor growth inhibition.

1. Sabari JK, et al. Nat Rev Clin Oncol. 2017;14(9):549–61. 2. Saunders LR, et al. Sci Transl Med. 2015;7(302):302ra136. 3. Petrelli F, et al. Mol Clin Oncol. 2021;15(4):218. 4. Liu LN, et al. Poster presented at: ELCC; March 22, 2024; Prague, Czech Republic.

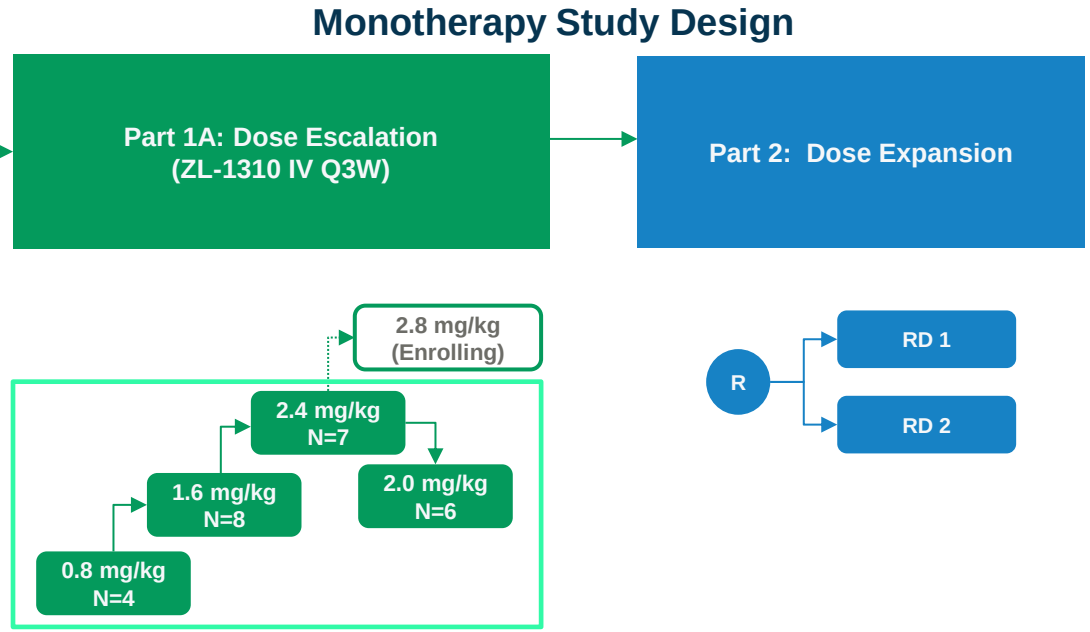
# ZL-1310-001 Study Overview (NCT06179069)

- Phase I, open-label, dose-escalation and expansion study of ZL-1310 as monotherapy and in combination with atezolizumab for r/r metastatic SCLC
- We report data from the ongoing monotherapy dose escalation (Part 1A), with 25 patients enrolled across 4 cohorts
  - All 25 patients were evaluable for safety; 19 pts with at least one post baseline tumor assessment are response evaluable

**Patients with:**

- metastatic or extensive-stage SCLC with ≥1 prior PBC regimen and ≤3 prior regimens; prior DLL3-targeted therapy allowed
- asymptomatic brain metastasis (previously treated or untreated) allowed

| Part 1A: Dose Escalation |
|---|
| **Primary Endpoints** |
| DLT, TEAEs, and SAEs |
| **Secondary Endpoints** |
| ORR, DOR, PFS, DCR, and OS |
| PK parameters of ZL-1310, total antibody, and unconjugated payload |




Data cut-off: October 10, 2024

DCR: disease control rate; DLT: dose-limiting toxicity; DOR: duration of response; IV: intravenous; ORR: objective response rate; OS: overall survival; PBC: platinum-based chemotherapy; PFS: progression-free survival; PK: pharmacokinetic; Q3W: once every 3 weeks; RD: recommended dose; r/r: relapsed/refractory; SAE: serious adverse event; SCLC: small cell lung cancer; TEAE: treatment emergent adverse event.

# Baseline Demographics and Clinical Characteristics

All patients received a platinum-based regimen as first-line therapy


of all patients received at least two prior regimens of systemic therapy


of patients received prior anti-PD-(L)1 therapy, and one patient received prior DLL3 bi-specific therapy

| Characteristics | | 0.8 mg/kg (N=4) | 1.6 mg/kg (N=8) | 2.0 mg/kg (N=6) | 2.4 mg/kg (N=7) | Total (N=25) |
|---|---|---|---|---|---|---|
| Median age, years (range) | | 67.0 (59, 69) | 64.0 (36, 73) | 68.5 (64, 76) | 66.0 (59, 79) | 67 (36, 79) |
| Sex, n (%) | Male | 2 (50.0) | 6 (75.0) | 5 (83.3) | 2 (28.6) | 15 (60.0) |
| | Female | 2 (50.0) | 2 (25.0) | 1 (16.7) | 5 (71.4) | 10 (40.0) |
| Race, n (%) | Asian | 1 (25.0) | 5 (62.5) | 3 (50.0) | 2 (28.6) | 11 (44.0) |
| | White | 3 (75.0) | 3 (37.5) | 3 (50.0) | 5 (71.4) | 14 (56.0) |
| ECOG, n (%) | 0 | 1 (25.0) | 3 (37.5) | 1 (16.7) | 2 (28.6) | 7 (28.0) |
| | 1 | 3 (75.0) | 5 (62.5) | 5 (83.3) | 5 (71.4) | 18 (72.0) |
| Brain metastasis[1], n (%) | Yes | 2 (50.0) | 2 (25.0) | 2 (33.3) | 1 (14.3) | 7 (28.0) |
| No. of prior regimen, n (%) | 1 | 1 (25.0) | 6 (75.0) | 2 (33.3) | 2 (28.6) | 11 (44.0) |
| | 2 | 3 (75.0) | 2 (25.0) | 2 (33.3) | 2 (28.6) | 9 (36.0) |
| | 3 | 0 | 0 | 2 (33.3) | 3 (42.9) | 5 (20.0) |
| With prior anti-PD-(L)1 therapy, n (%) | | 4 (100) | 7 (87.5) | 5 (83.3) | 7 (100) | 23 (92.0) |
| With prior DLL3 bi-specific , n (%) | | 0 | 0 | 0 | 1 (14.3) | 1 (4.0) |

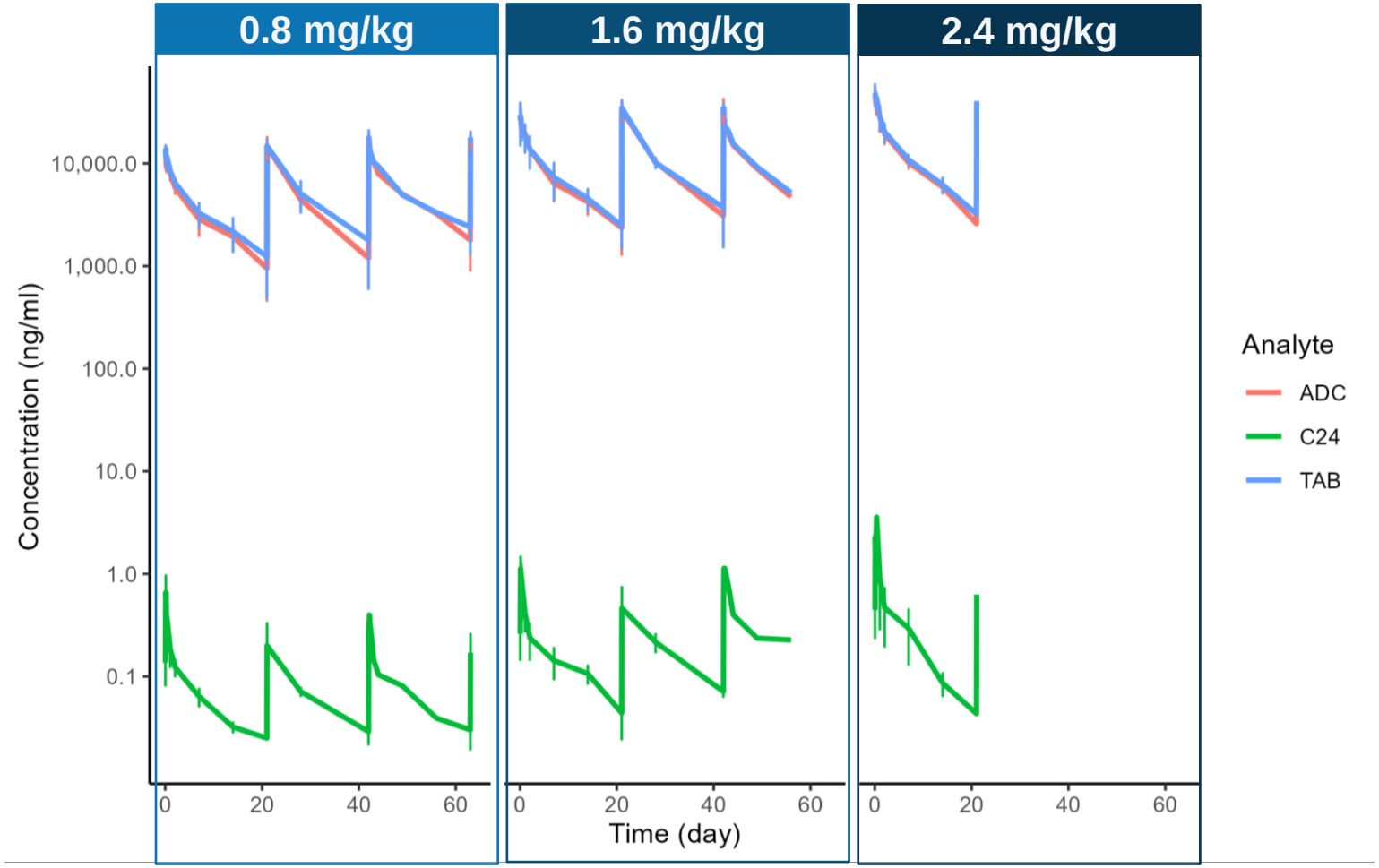
Data cut-off: October 10, 2024

[1] Two patients had untreated asymptomatic brain metastases at baseline

DLL3: delta-like ligand 3; ECOG: Eastern Cooperative Oncology Group.

# Preliminary Clinical Pharmacokinetics

- Systemic exposure of ADC and total antibody are approximately dose proportional
- Relatively low concentration of payload indicates high stability of linker-payload in circulation
- The mean terminal half-life of ZL-1310 ranged from 6 to 7 days across three dose levels




Data cut-off: October 10, 2024
12 PK evaluable patients in dose levels 0.8 - 2.4 mg/kg were included.
TAB: total antibody; ADC: antibody-drug conjugate; C24: cytotoxic payload; solid line: mean concentration; error bar: standard deviation.

# **ZL-1310:** Safety Summary of Treatment Emergent Adverse Events (TEAEs)

| TEAE, n (%) | Total (N=25) |
|---|---|
| **Any TEAE** | **24 (96.0)** |
| TEAEs Related to ZL-1310 | 21 (84.0) |
| **Grade ≥3 TEAE** | **10 (40.0)** |
| Grade ≥3 TEAE Related to ZL-1310 | 5 (20.0) |
| **Serious TEAE** | **6 (24.0)** |
| Serious TEAE Related to ZL-1310 | 2 (8.0) |
| **TEAE Leading to Dose Interruption** | **5 (20.0)** |
| TEAE Related to ZL-1310 Leading to Dose Interruption | 2 (8.0) |
| **TEAE Leading to Dose Reduction** | **3 (12.0)** |
| TEAE Related to ZL-1310 Leading to Dose Reduction | 3 (12.0) |
| **TEAE Leading to Drug Discontinuation** | **0** |
| TEAE Related to ZL-1310 Leading to Drug Withdrawn | 0 |
| **TEAE Leading to Death** | **0** |
| **DLT Event** | **1** |

- One transient DLT (G4 neutropenia/ thrombocytopenia) was reported in 1 out of 7 patients treated in the 2.4 mg/kg cohort
- TEAEs related to ZL-1310 leading to dose reduction included:
  - Decreased appetite (G2), malaise (G2), hyponatraemia (G3), vomiting (G2), neutrophil count decreased (G4), and platelet count decreased (G4)
- No TEAE led to drug discontinuation or death

Data cut-off: October 10, 2024
DLT: dose-limiting TEAE: treatment emergent adverse event.

# **ZL-1310:** Most Common (≥15%) and Grade ≥3 TEAEs, Regardless of Causality

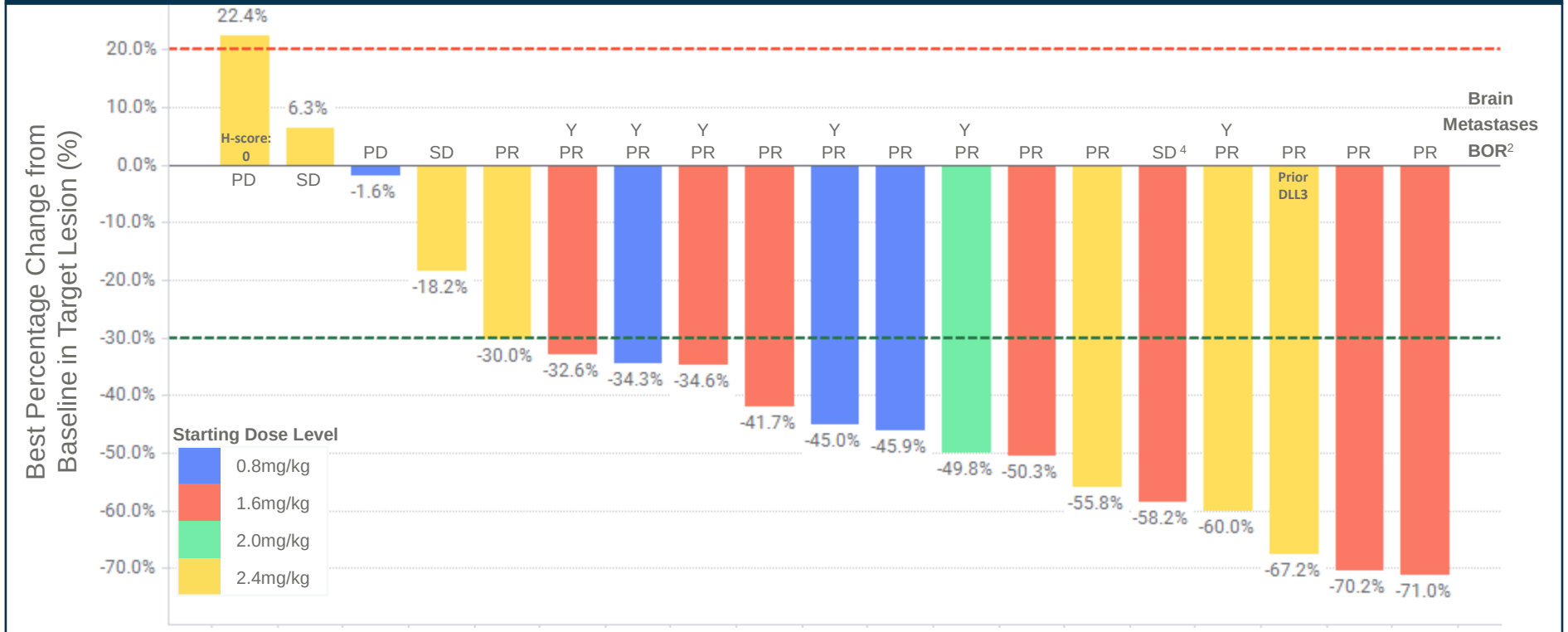
| Preferred Term | 0.8 mg/kg (N=4) | | 1.6 mg/kg (N=8) | | 2.0 mg/kg (N=6) | | 2.4 mg/kg (N=7) | | Total (N=25) | |
|---|---|---|---|---|---|---|---|---|---|---|
| | All Grade | Grade ≥3 | All Grade | Grade ≥3 | All Grade | Grade ≥3 | All Grade | Grade ≥3 | All Grade | Grade ≥3 |
| Any TEAE | 4 (100) | 2 (50.0) | 7 (87.5) | 2 (25.0) | 6 (100) | 2 (33.3) | 7 (100) | 4 (57.1) | 24 (96.0) | 10 (40.0) |
| Nausea | 1 (25.0) | 0 | 3 (37.5) | 0 | 2 (33.3) | 0 | 6 (85.7) | 0 | 12 (48.0) | 0 |
| Anaemia | 1 (25.0) | 0 | 4 (50.0) | 0 | 3 (50.0) | 0 | 3 (42.9) | 1 (14.3) | 11 (44.0) | 1 (4.0) |
| Neutrophil count decreased | 0 | 0 | 3 (37.5) | 0 | 4 (66.7) | 1 (16.7) | 3 (42.9) | 2 (28.6) | 10 (40.0) | 3 (12.0) |
| White blood cell count decreased | 0 | 0 | 3 (37.5) | 0 | 3 (50.0) | 1 (16.7) | 3 (42.9) | 0 | 9 (36.0) | 1 (4.0) |
| Decreased appetite | 0 | 0 | 4 (50.0) | 0 | 1 (16.7) | 0 | 2 (28.6) | 0 | 7 (28.0) | 0 |
| Hyponatraemia | 1 (25.0) | 0 | 2 (25.0) | 0 | 1 (16.7) | 0 | 1 (14.3) | 1 (14.3) | 5 (20.0) | 1 (4.0) |
| Dizziness | 1 (25.0) | 0 | 2 (25.0) | 0 | 1 (16.7) | 0 | 0 | 0 | 4 (16.0) | 0 |
| Fatigue | 0 | 0 | 1 (12.5) | 0 | 1 (16.7) | 0 | 2 (28.6) | 0 | 4 (16.0) | 0 |
| Malaise | 0 | 0 | 2 (25.0) | 0 | 2 (33.3) | 0 | 0 | 0 | 4 (16.0) | 0 |
| Platelet count decreased | 0 | 0 | 0 | 0 | 2 (33.3) | 0 | 2 (28.6) | 1 (14.3) | 4 (16.0) | 1 (4.0) |

- The most common TEAEs included hematologic and gastrointestinal events
- Hematological toxicity was dose dependent with few to no G3+ events up to 2.4 mg/kg
- Gastrointestinal toxicity was G1/2

Data cut-off: October 10, 2024
TEAE: treatment-emergent adverse event.

# ZL-1310: Anti-Tumor Activity (1 of 2)

## Changes in Target Lesion Size by Dose Levels (n=19)[1]




| | Total (N=19)[1] |
|---|---|
| **ORR[2], n (%) [95% CI]** | 14 (74) [48.8, 90.9] |
| **BOR, n (%)** | |
| CR | 0 |
| PR[3] | 14 (74) |
| SD[4] | 3 (16) |
| PD | 2 (10) |

- Nearly all patients with post-baseline scans had a reduction in target lesions
  - Median time to response was 1.38 months (range: 1.2, 2.8)[2]
  - Of the 6 response evaluable patients with brain metastases at baseline, all achieved a PR

Data cut-off: October 10, 2024

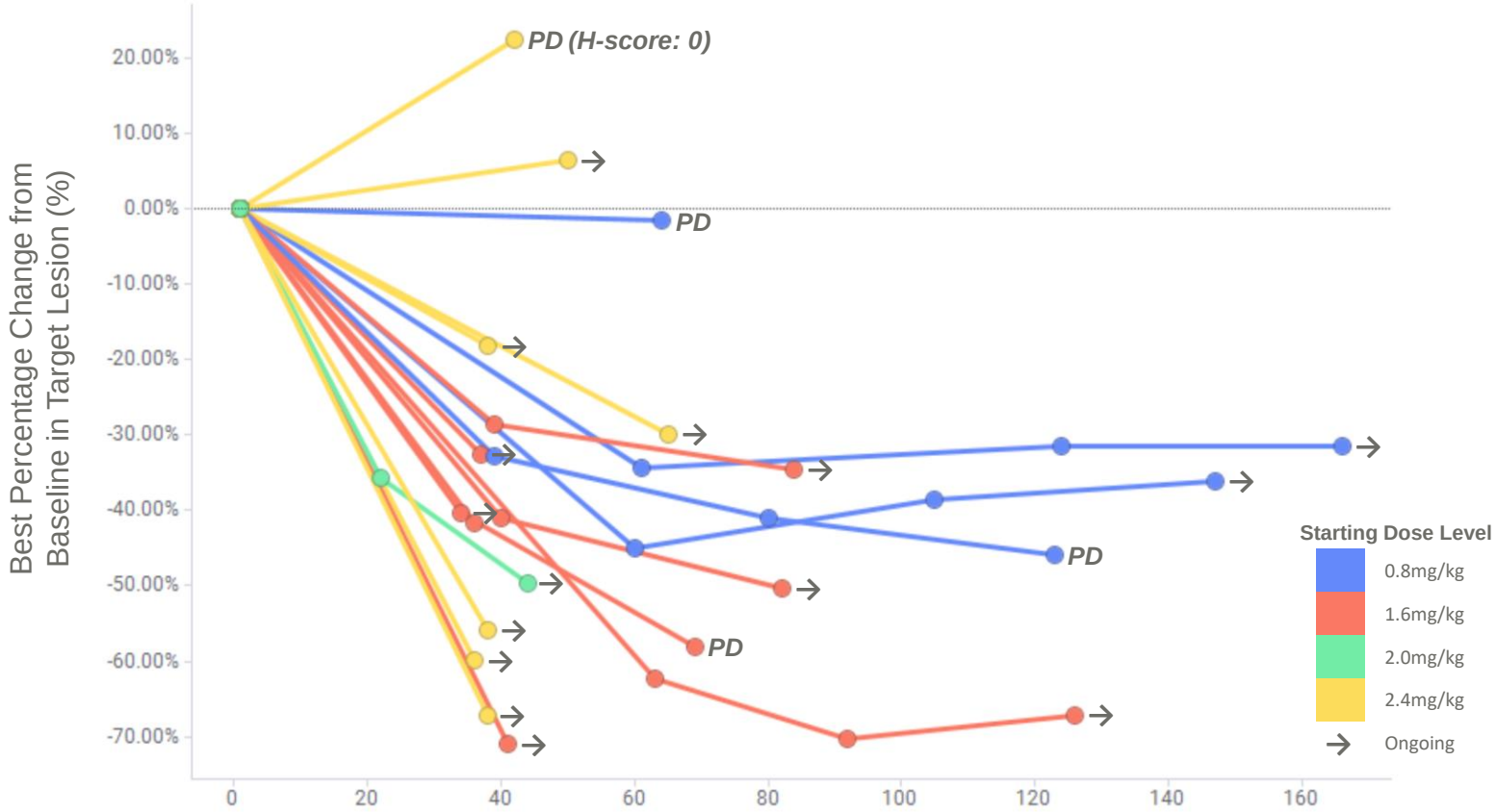
[1] Patients with measurable disease at baseline and ≥1 post-baseline tumor scans are included in waterfall and overall response calculation; [2] Included unconfirmed responses; [3] Including 5 patients with confirmed PR and for the 9 patients with unconfirmed PR, the responses are ongoing at data cutoff; [4] One patient had unconfirmed PR followed by PD, thus the overall response is SD.

BOR: best overall response; CI: confidence interval; CR: complete response; ORR: objective response rate; PD: progressive disease; PR: partial response; SD: stable disease ; Y: patient had brain metastases at baseline

# ZL-1310: Anti-Tumor Activity (2 of 2)

- The median follow-up was 2.4 months (range: 0.3-6.5)
  - DOR and PFS are not yet mature
- At data cut-off, 13 of 14 responders remain on study treatment
  - 0.8 mg/kg cohort: 2/3
  - 1.6 mg/kg cohort: 6/6
  - 2.0 mg/kg cohort: 1/1
  - 2.4 mg/kg cohort: 4/4

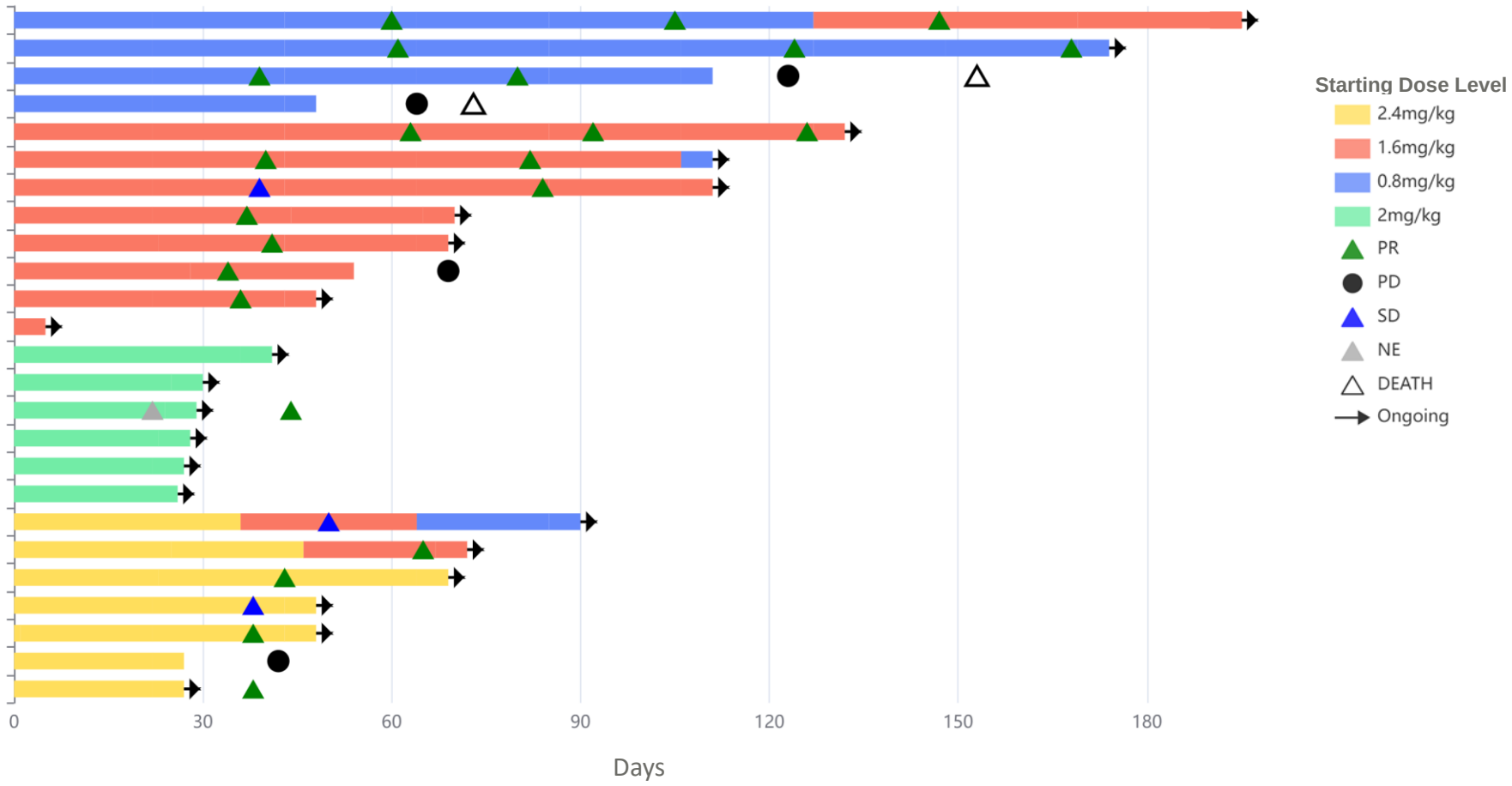
**Changes in Target Lesion Size over time by Dose Levels (n=19)**




Data cut-off: October 10, 2024
DOR: duration of response; PD: progressive disease; PFS: progression-free survival.

# ZL-1310: Responses and Duration by Dose Level

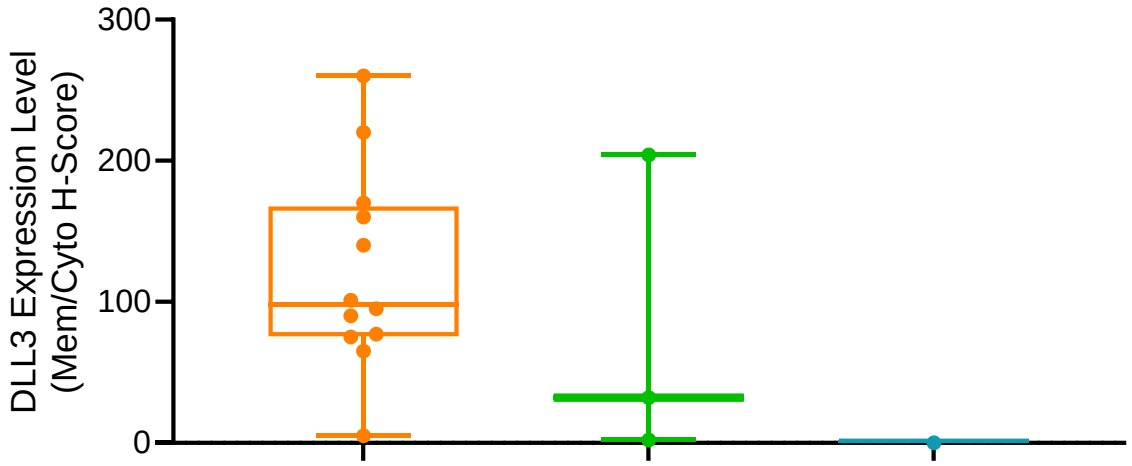
- As of the data cutoff, 20 of 25 patients (80%) remain on study treatment
  - 0.8 mg/kg cohort: 2/4 (50%)
  - 1.6 mg/kg cohort: 6/8 (75%)
  - 2.0 mg/kg cohort: 6/6 (100%)
  - 2.4 mg/kg cohort: 6/7 (86%)
- Of the 14 responders, 13 remain on treatment with one patient ongoing at 6.5+ months




Data cut-off: October 10, 2024
NE: not evaluable; PD: progressive disease; PR: partial response; SD: stable disease

# ZL-1310: Preliminary DLL3 Correlative Results

**DLL3 Level by BOR[1] Status for DLL3 Evaluable[2] Patients (n=16)**




- Baseline median H-score was 92.5 with a range of 0 (n=1) to 260
- Objective responses observed in patients with H-scores as low as 5
  - The range of H-score is 5 to 260 for patients with PR
  - Clinical tumor reduction observed in patient with an H-score of 2
  - Patient treated with prior tarlatamab had an H-score of 170 and had a PR

Data cut-off: October 10, 2024

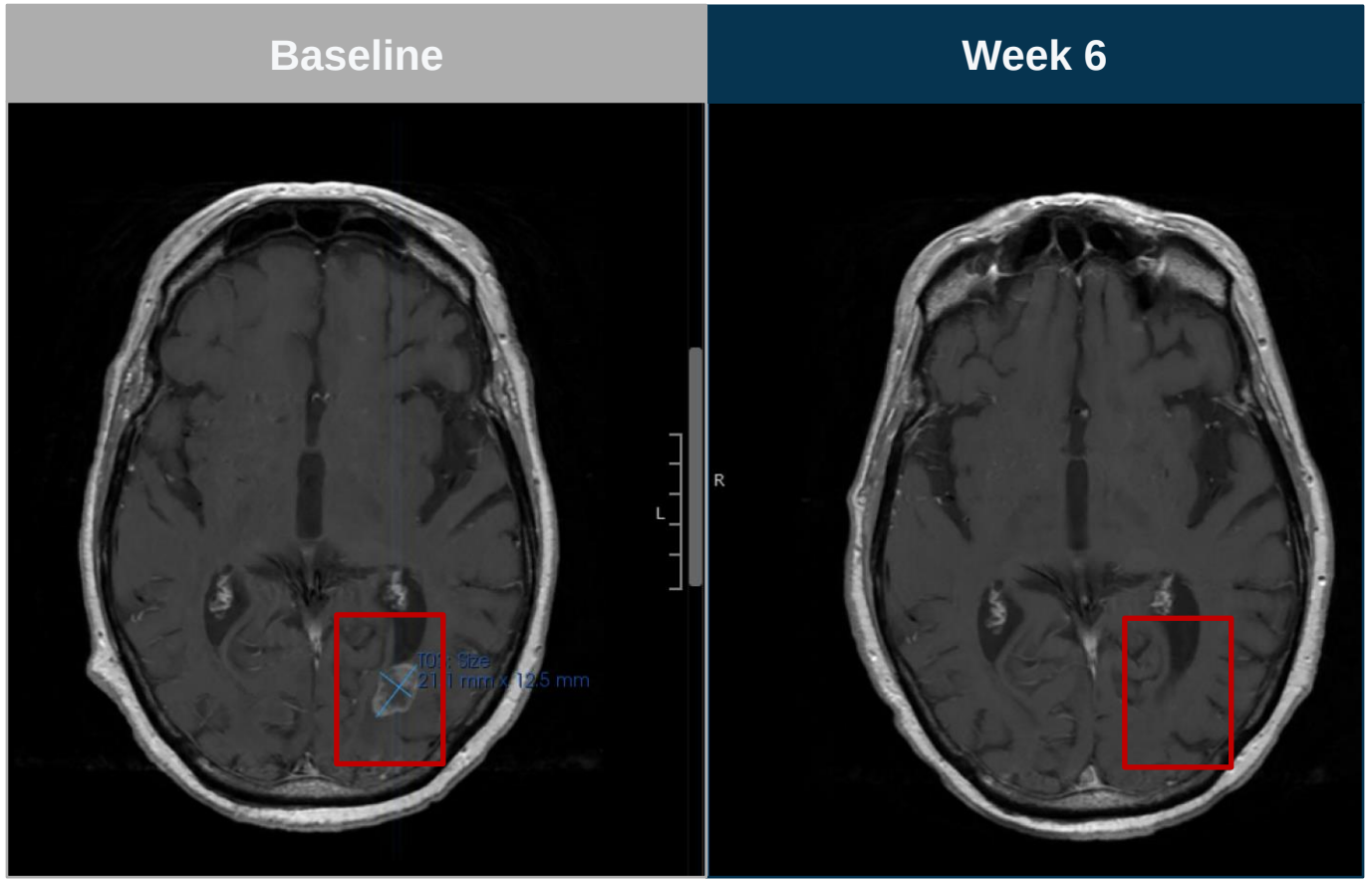
[1]BOR and ORR includes both confirmed and unconfirmed responses

[2] Tumor biopsy samples were retrospectively examined for DLL3 protein level by IHC in biomarker-evaluable patients who are evaluable for overall response at all dose levels (n = 16). H-score of the combined membrane/cytosol staining was used for the correlative analysis to reflect the unique staining pattern of DLL3 in SCLC tumor cells.

BOR: best overall response; IHC: immunohistochemistry; PD: progressive disease; PR: partial response; SD: stable disease

# **Case Study 1:** PR in a Patient with Untreated Brain Metastases

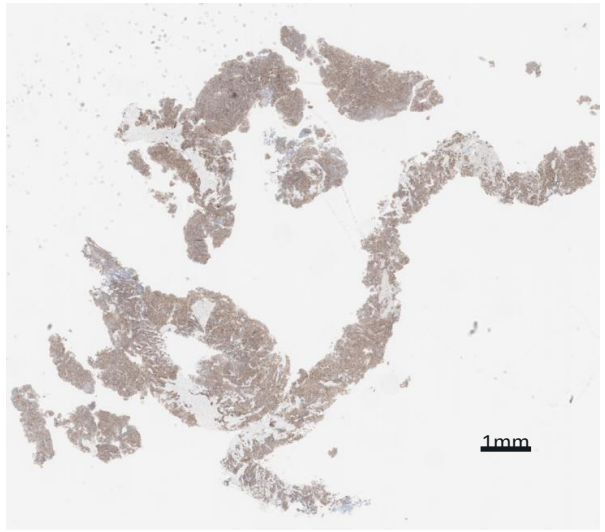
- 67-year-old male with extensive SCLC and untreated brain metastases at baseline
  - Prior regimen: EC + Atezolizumab
  - Prior radiation: focal lung (50 Gy)
  - No radiation to brain metastases at baseline
- Received ZL-1310 0.8 mg/kg Q3W
  - PR at Week 6 with a 45% tumor reduction



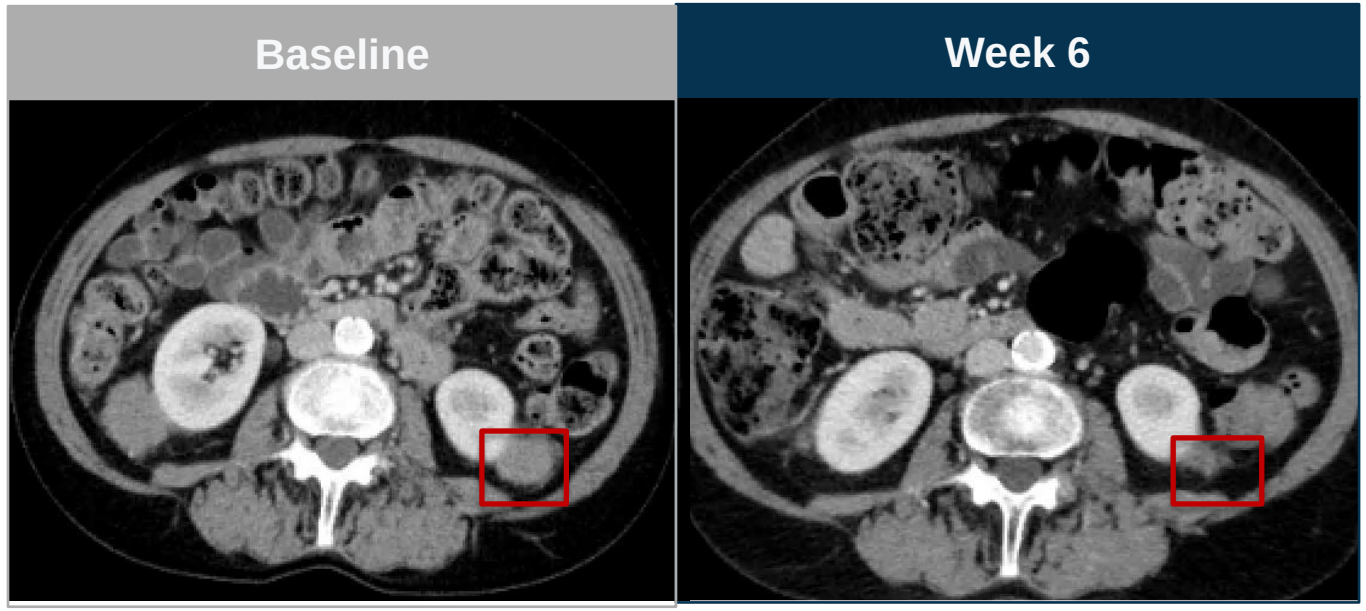

EC: Etoposide and carboplatin; PR: partial response; Q3W: once every 3 weeks; SCLC: small cell lung cancer.

# **Case Study 2:** PR in a Patient Who Progressed After DLL3 Bi-Specific Treatment

- 66-year-old female with extensive SCLC including lung, liver and retroperitoneum at baseline treated with ZL-1310 at 2.4 mg/kg Q3W
- Prior regimens (BOR): 1. EC + durvalumab (PR), 2. Tarlatamab (PD), 3. Alisertib (aurora kinase inhibitor; PD)




**DLL3 expression (H-score: 170) after tarlatamab treatment**




**PR at wk 6 with a 67% tumor reduction**

BOR: best overall response; DLL3: delta-like ligand 3; EC: Etoposide and carboplatin; PD: progressive disease; PR: partial response; Q3W: once every 3 weeks; SCLC: small cell lung cancer.

# Conclusions


- Well tolerated at therapeutic dose levels
- Demonstrates antitumor activity across all dose levels in 2+ line SCLC with an ORR[1] of 74% with 13 of 14 responders ongoing including patients treated at the lowest dose tested of 0.8 mg/kg, patients with brain metastases and prior DLL3 therapy
- Data support further development of ZL-1310 as a single agent and in combination in earlier lines

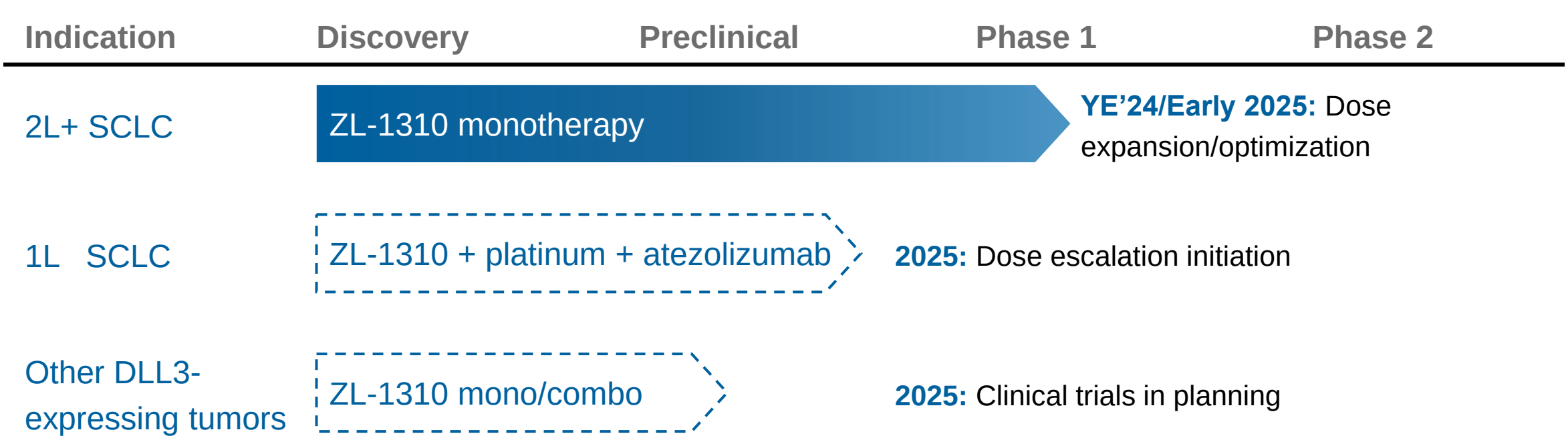
Data cut-off: October 10, 2024
[1] Included both confirmed and unconfirmed responses
DLL3: delta-like ligand 3; ORR: objective response rate; SCLC: small cell lung cancer.

**Rafael Amado, MD**

President, Head of Global Research and Development, Zai Lab

- ZL-1310 (DLL3 ADC) Highlights from ENA 2024
- **Closing Remarks**
- Q&A

# ZL-1310: Next Steps




***Advancing ZL-1310 into earlier lines of SCLC treatment and other opportunities where there is unmet need and opportunity to serve patients across the continuum***

# Building a Globally Differentiated Pipeline

| | Program | Preclinical | Phase I | Phase II | Key Differentiation |
|---|---|---|---|---|---|
| Oncology | **ZL-1310 (DLL3 ADC)** | SCLC | | | • Topo1 payload with high tumor accumulation, better permeability, and fast systemic clearance |
| Oncology | **ZL-1218 (CCR8)** | Solid tumor | | | • Novel antibody targeting CCR8 receptors<br>• Demonstrated an encouraging pre-clinical profile |
| Oncology | **ZL-6301 (ROR1 ADC)** | Solid tumor | | | • Next-gen ADC targeting ROR1 with potential to treat solid tumors<br>• Highly differentiated novel linker-payload technology compared to earlier ROR1-targeted ADCs |
| Oncology | **ZL-2210 (Undisclosed)** | Solid tumor | | | • Next-gen technology targeting DDR pathway |
| Oncology | **ZL-6201 (Undisclosed)** | Solid tumor | | | • Next-gen ADC platform |
| Immunology | **ZL-1102 (IL-17 Humabody®)** | Psoriasis | | | • Topical formulation of a biologic and demonstrated penetration of psoriatic skin resulting in clinical response |
| Immunology | **ZL-1503 (IL31xIL13)** | Atopic Dermatitis | | | • Strong scientific rationale and clinically validated targets for AD<br>• Next-generation IL-13/IL-31 therapeutic may provide faster onset and superior efficacy through rapid relief of pruritus |

**Multiple Undisclosed IND-enabling Assets, with the Goal to Generate at Least One IND per Year**

**Alex Spira, MD, PhD, FACP, FASCO**

Co-Director, Virginia Cancer Specialists Research Institute

**Rafael Amado, MD**

President, Head of Global Research and Development, Zai Lab

ZL-1310 (DLL3 ADC) Highlights from ENA 2024

Closing Remarks

**Q&A**