

# zaiLab

## ZL-1310 ASCO 2025 Highlights

June 2, 2025

NASDAQ:ZLAB | HKEX:9688

© 2024. Zai Lab. All Rights Reserved.



# 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 small cell lung cancer (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.

Our SEC filings can be found on our website at [www.zailaboratory.com](http://www.zailaboratory.com) and on the SEC’s website at <http://www.sec.gov>. This presentation does not constitute an offer to sell or the solicitation of an offer to buy any securities of Zai Lab Limited.

# Agenda



## **Manish R. Patel, MD**

Director of Drug Development,  
Florida Cancer Specialists

Associate Director of Drug  
Development, Sarah Cannon  
Research Institute



## **Rafael Amado, MD**

President, Head of Global  
Research and Development,  
Zai Lab



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

Co-Director, Virginia Cancer  
Specialists Research Institute

**ZL-1310 (DLL3 ADC) Highlights from ASCO 2025**

**Next Steps and Conclusions**

**Q&A with Dr. Amado and Dr. Spira**

# Agenda



## Manish R. Patel, MD

Director of Drug Development,  
Florida Cancer Specialists

Associate Director of Drug  
Development, Sarah Cannon  
Research Institute

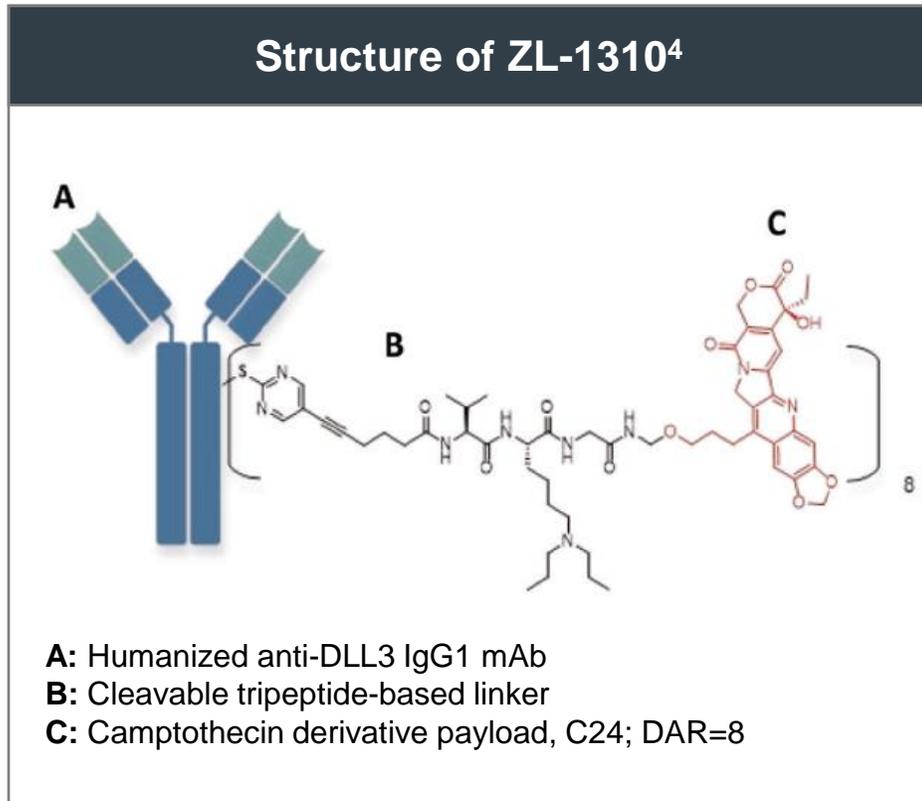
- Hematologist/Medical Oncologist
- Subspecializes in Early Phase clinical trials based out of Sarasota, Florida
- Directs three Phase 1 units as part of the Florida program and provides care for all malignancies on Phase 1 clinical trials
- Received medical degree from the University of Miami School of Medicine and completed Internal Medicine residency training at Vanderbilt University in Nashville, TN
- Fellowship in Hematology/Oncology at the H. Lee Moffitt Cancer Center & Research Institute/University of South Florida in Tampa, FL

**ZL-1310 (DLL3 ADC) Highlights from ASCO 2025**

Next Steps and Conclusions

Q&A with Dr. Amado and Dr. Spira

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



- Small cell lung cancer (SCLC) accounts for ~15% of the lung cancer overall with **~270,000 annual deaths** worldwide with a high unmet medical need<sup>1-2</sup>
- SCLC is a high-grade neuroendocrine tumor with a **high proliferation rate, early metastases, and poor prognosis**<sup>3</sup>
- DLL3 is a validated target for neuroendocrine tumors and is highly expressed in SCLC<sup>4</sup>
- Zocilurtatug pelitecan or **ZL-1310**, a DLL3-targeted antibody drug conjugate (ADC), demonstrates promising clinical activity in patients with relapsed/refractory (r/r) ES-SCLC<sup>5</sup>
  - Potent topoisomerase 1 inhibitor payload
  - High picomolar antibody affinity
  - Drug-to-antibody ratio (DAR) of 8
  - Stable, cleavable tripeptide-based linker
  - Strong bystander antitumor effect

# Study Design of the Ongoing Phase 1 Study in ES-SCLC (Monotherapy)

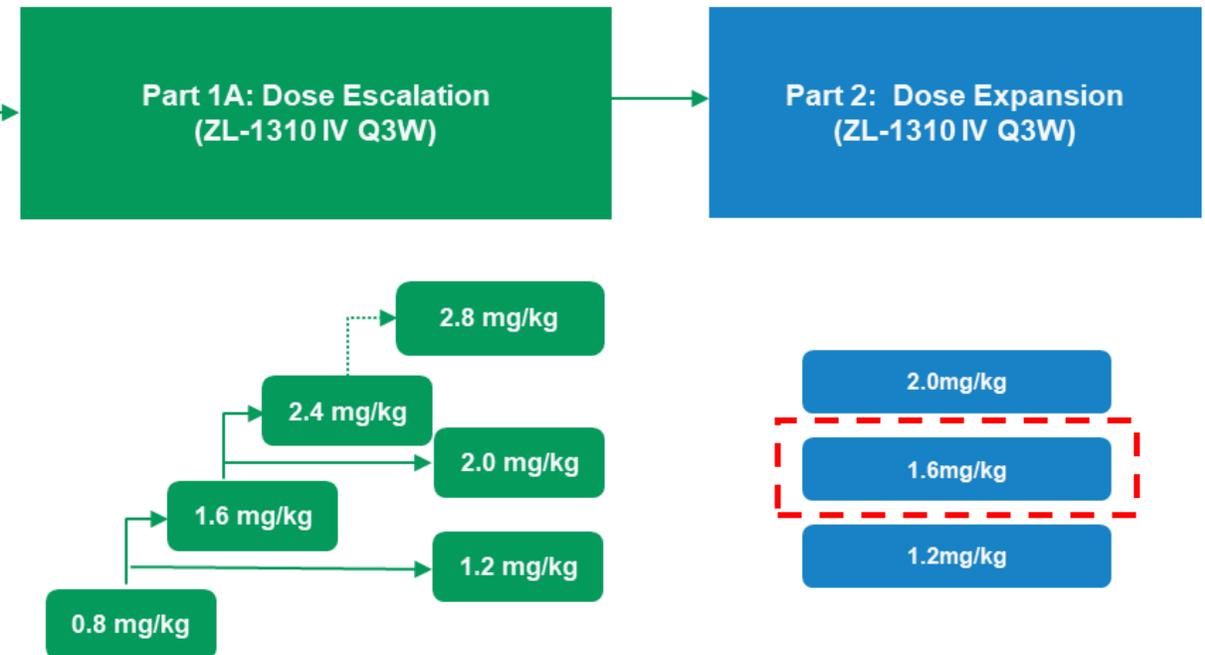
- Phase I, open-label, dose-escalation and expansion study of ZL-1310 as monotherapy and in combination with atezolizumab for r/r metastatic SCLC
- We report data updated ZL-1310 monotherapy data with additional patients and follow-up from the ongoing Phase I trial

## Patients with:

- metastatic or extensive-stage SCLC with  $\geq 1$  prior platinum-based chemotherapy regimen
- asymptomatic brain metastasis (previously treated or untreated) allowed
- prior DLL3-targeted therapy allowed

	Part 1A	Part 2
Primary Endpoints	<ul style="list-style-type: none"> <li>Safety: DLT, TEAEs, and SAEs</li> </ul>	<ul style="list-style-type: none"> <li>TEAEs and SAEs</li> <li>ORR</li> </ul>
Secondary Endpoints	<ul style="list-style-type: none"> <li>Efficacy: ORR, DOR, PFS, DCR, and OS</li> </ul>	<ul style="list-style-type: none"> <li>DOR, PFS, DCR, and OS</li> </ul>
	<ul style="list-style-type: none"> <li>PK and PD parameters of ZL-1310, total antibody, and unconjugated payload</li> </ul>	

## Monotherapy Study Design



# Baseline & Disease Characteristics

Baseline and Disease Characteristics								
		0.8 mg/kg (N=4)	1.2 mg/kg (N=11)	1.6 mg/kg (N=35)	2.0 mg/kg (N=29)	2.4 mg/kg (N=7)	2.8 mg/kg (N=3)	Total (N=89)
<b>Median age, years (range)</b>		67.0 (59, 69)	68.0 (55, 80)	65.0 (36, 77)	63.0 (52, 77)	66.0 (59, 79)	60.0 (58, 73)	65.0 (36, 80)
<b>Sex, n (%)</b>	Male	2 (50%)	5 (45%)	23 (66%)	19 (65%)	2 (29%)	1 (33%)	52 (58%)
	Female	2 (50%)	6 (55%)	12 (34%)	10 (35%)	5 (71%)	2 (67%)	37 (42%)
<b>Race, n (%)</b>	Asian	1 (25%)	0	13 (37%)	9 (31%)	2 (29%)	3 (100%)	28 (32%)
	White	3 (75%)	9 (82%)	21 (60%)	20 (69%)	5 (71%)	0	58 (65%)
<b>ECOG, n (%)</b>	0	1 (25%)	2 (18%)	15 (43%)	9 (31%)	2 (29%)	0	29 (33%)
	1	3 (75%)	9 (82%)	20 (57%)	20 (69%)	5 (71%)	3 (100%)	60 (67%)
<b>Brain metastasis, n (%)*</b>	Yes	2 (50%)	4 (36%)	8 (23%)	9 (31%)	2 (29%)	2 (67%)	27 (30%)
<b>No. of prior therapy line, n (%)</b>	1	2 (50%)	7 (64%)	16 (46%)	11 (38%)	4 (57%)	2 (67%)	42 (47%)
	2	2 (50%)	3 (27%)	11 (31%)	11 (38%)	1 (14%)	1 (33%)	29 (33%)
	≥3	0	1 (9%)	8 (23%)	7 (24%)	2 (29%)	0	18 (20%)
<b>With prior anti-PD-(L)1 therapy, n (%)</b>		4 (100%)	10 (91%)	31 (89%)	25 (86%)	7 (100%)	3 (100%)	80 (90%)
<b>With prior topotecan/irinotecan, n (%)</b>		0	2 (18%)	7 (20%)	9 (31%)	1 (14%)	1 (33%)	20 (23%)
<b>With prior lurbinectedin, n (%)</b>		1 (25%)	2 (18%)	4 (11%)	5 (17%)	0	0	12 (14%)
<b>With prior DLL3 bi-specific Ab, n (%)</b>		0	2 (18%)	4 (11%)	3 (10%)	1 (14%)	0	10 (11%)

As of 1 Apr 2025, 89 pts were enrolled across 6 dose cohorts:

- 47% pts received 1 prior line of therapy, 53% pts received 2 or more
- 1.6, 2.0 and 2.4 mg/kg arms included 23%, 24% and 29% pts, respectively, had 3 or more prior lines
- 90% pts received prior anti-PD-(L)1 therapy
- 30% pts presented with brain metastasis at baseline, of which 8 were untreated

Note: \*Patients with brain metastases listed as target or non-target lesion, includes both previously treated and untreated lesions.

# Safety

## Safety Summary

TEAE, n (%)	<2.0mg/kg (N=50)	≥2.0mg/kg (N=39)	Total (N=89)
<b>Any TEAE</b>	42 (84%)	37 (95%)	79 (89%)
Grade ≥3	9 (18%)	17 (44%)	26 (29%)
Leading to Dose Interruption	8 (16%)	17 (44%)	25 (28%)
Leading to Dose Reduction	2 (4%)	4 (10%)	6 (7%)
Leading to Drug Discontinuation	0	5 (13%)	5 (6%)
Leading to Death	0	2 (5%)	2 (2%)
<b>Serious TEAE</b>	11 (22%)	8 (21%)	19 (21%)
<b>TEAEs Related to ZL-1310</b>	29 (58%)	36 (92%)	63 (73%)
Grade ≥3	3 (6%)	17 (44%)	20 (23%)
Leading to Dose Interruption	3 (6%)	14 (36%)	17 (19%)
Leading to Dose Reduction	2 (4%)	4 (10%)	6 (7%)
Leading to Drug Discontinuation	0	5 (13%)	5 (6%)
Leading to Death	0	1 (3%)	1 (1%)
<b>Serious TEAE Related to ZL-1310</b>	2 (4%)	5 (13%)	7 (8%)

- As of 1 Apr 2025, 89 pts received at least one dose of ZL-1310 and included in the safety analysis
- ZL-1310 demonstrated a well-tolerated safety profile
- **In doses < 2.0mg/kg:**
  - **Grade ≥3 TRAEs of 6% (3)**
  - **Serious TRAEs of 4% (2)**
  - **No TRAEs leading to drug discontinuation or death**

# Safety (Cont'd)

## TRAEs in ≥ 10% of the Patients

n (%)	<2.0mg/kg (N=50)		≥2.0mg/kg (N=39)		Total (N=89)	
	All Grade	Grade ≥3	All Grade	Grade ≥3	All Grade	Grade ≥3
Any TRAE	29 (58%)	3 (6%)	36 (92%)	17 (44%)	65 (73%)	20 (23%)
Anemia	15 (30%)	1 (2%)	21 (54%)	9 (23%)	36 (40%)	10 (11%)
Neutropenia*	7 (14%)	2 (4%)	20 (51%)	10 (26%)	27 (30%)	12 (14%)
Nausea	10 (20%)	0	13 (33%)	0	23 (26%)	0
Leukopenia*	4 (8%)	0	16 (41%)	3 (8%)	20 (23%)	3 (3%)
Thrombocytopenia*	2 (4%)	0	13 (33%)	4 (10%)	15 (17%)	4 (5%)
Decreased appetite	8 (16%)	0	5 (13%)	0	13 (15%)	0
Fatigue	4 (8%)	0	6 (15%)	1 (3%)	10 (11%)	1 (1%)
Lymphopenia*	3 (6%)	0	6 (15%)	2 (5%)	9 (10%)	2 (2%)
Pneumonitis/ILD	2 (4%)	0	7 (18%)	2 (5%)	9 (10%)	2 (2%)

- Grade ≥3 hematologic toxicity was
  - **Minimal in the low-dose group (4% neutropenia)**
  - Manageable even at the higher dose levels (26% neutropenia)
- **In doses < 2.0mg/kg:**
  - **No Grade ≥3 ILD**
  - **2 patients with ILD were Grade 1 and have been resolved and resumed ZL-1310 treatment**

Note: \*Neutropenia includes neutrophil decrease; Leukopenia includes white blood cell count decrease; Thrombocytopenia includes platelet count decrease; Lymphopenia includes lymphocyte count decrease.

# Efficacy – Dose Escalation Cohort

## Best Overall Response in Dose Escalation (N=28)

	0.8 mg/kg (N=4)	1.6 mg/kg (N=8)	2.0 mg/kg (N=6)	2.4 mg/kg (N=7)	2.8 mg/kg (N=3)	Total (N=28)
Best Overall Response – n (%)						
CR*	0	0	0	1 (14%)	0	1 (4%)
PR*	3 (75%)	5 (63%)	4 (67%)	3 (43%)	3 (100%)	18 (64%)
Stable Disease	0	3 (38%)	2 (33%)	2 (29%)	0	7 (25%)
Progressive Disease	1 (25%)	0	0	1 (14%)	0	2 (7%)
ORR* – n (%)	3 (75%)	5 (63%)	4 (67%)	4 (57%)	3 (100%)	<b>19 (68%)</b>
Disease Control Rate – n (%)	3 (75%)	8 (100%)	6 (100%)	6 (86%)	3 (100%)	<b>26 (93%)</b>

As of data cut-off: Median follow-up time was 6.9 months (95% CI 2.4, 12.2)

- For the 28 pts in dose escalation:
  - **Confirmed ORR of 68%**
  - mDOR not yet reached
- Of the 19 responders in dose escalation:
  - 10 remain in response between 2.8 and 9.1 months from initial response
  - Half of ongoing responders are in response at approximately 6 months or above

Notes: \*All the responses are confirmed for 28 patients in the dose escalation cohort.

# Efficacy by Lines of Therapy

## Best Overall Response Across Lines of Therapy in All Patients (Dose Escalation and Dose Expansion, N=74)

	2 <sup>nd</sup> Line (N = 33)	3 <sup>rd</sup> Line (N=26)	> 3 <sup>rd</sup> Line (N=15)	All (N=74)
Best Overall Response – n (%)				
CR <sup>1</sup>	2 (6%)	0	0	2 (2%)
PR <sup>2</sup>	20 (61%)	11 (42%)	5 (34%)	36 (49%)
Stable Disease	10 (30%)	13 (50%)	8 (53%)	31 (42%)
Progressive Disease	1 (3%)	2 (8%)	2 (13%)	5 (7%)
ORR – n (%)	<b>22 (67%)</b>	11 (42%)	5 (33%)	38 (51%)
Confirmed	16 (49%)	7 (27%)	4 (27%)	27 (37%)
Pending confirmation <sup>3</sup>	6 (18%)	4 (15%)	1 (6%)	11 (14%)
Disease Control Rate – n (%)	<b>32 (97%)</b>	24 (92%)	13 (87%)	69 (93%)

As of data cut-off: Median treatment exposure was 2.8 months (95% CI 2.5, 3.4); Median follow-up time was 3.4 months (95% CI 2.8, 3.7)

Notes: \*Includes confirmed and unconfirmed responses. (1) Included 1 patient with confirmed CR and 1 patient with unconfirmed CR in patients with 1 prior line; (2) Included 15 patients with confirmed PR and 5 patients with unconfirmed PR in patients with 1 prior line; 7 patients with confirmed PR and 4 patients with unconfirmed PR in patients with 2 prior lines; 4 patients with confirmed PR and 1 patient with unconfirmed PR in patients with 3+ prior lines; (3) As the study is still ongoing, these responses are pending confirmation at the time of next tumor scan.

- 74 pts have had the opportunity to be followed to at least 1 post baseline tumor assessment
- **In 2L SCLC:**
  - **ORR\* of 67%**
  - **DCR of 97%**
- Across all lines of therapy:
  - Of the 38 responders, 29 remain on study
  - Response rates declined in later lines of therapy
  - 27 of 31 pts (87%) with stable disease remain on study

# Efficacy by Dose Levels in Patients with 1 Prior Line

## Best Overall Response in Patients with 1 Prior Line (N=33)

	0.8 mg/kg (N=2)	1.6 mg/kg (N=14)	≥2.0 mg/kg (N=17)	Total (N=33)
Best Overall Response – n (%)				
CR <sup>1</sup>	0	0	2 (12%)	2 (6%)
PR <sup>2</sup>	2 (100%)	11 (79%)	7 (41%)	20 (61%)
Stable Disease	0	3 (21%)	7 (41%)	10 (30%)
Progressive Disease	0	0	1 (6%)	1 (3%)
ORR – n(%)	2 (100%)	<b>11 (79%)</b>	9 (53%)	<b>22 (67%)</b>
Confirmed	2 (100%)	8 (57%)	6 (35%)	16 (49%)
Pending confirmation <sup>3</sup>	0 (0%)	3 (22%)	3 (18%)	6 (18%)
Disease Control Rate – n (%)	2 (100%)	<b>14 (100%)</b>	16 (94%)	<b>32 (97%)</b>

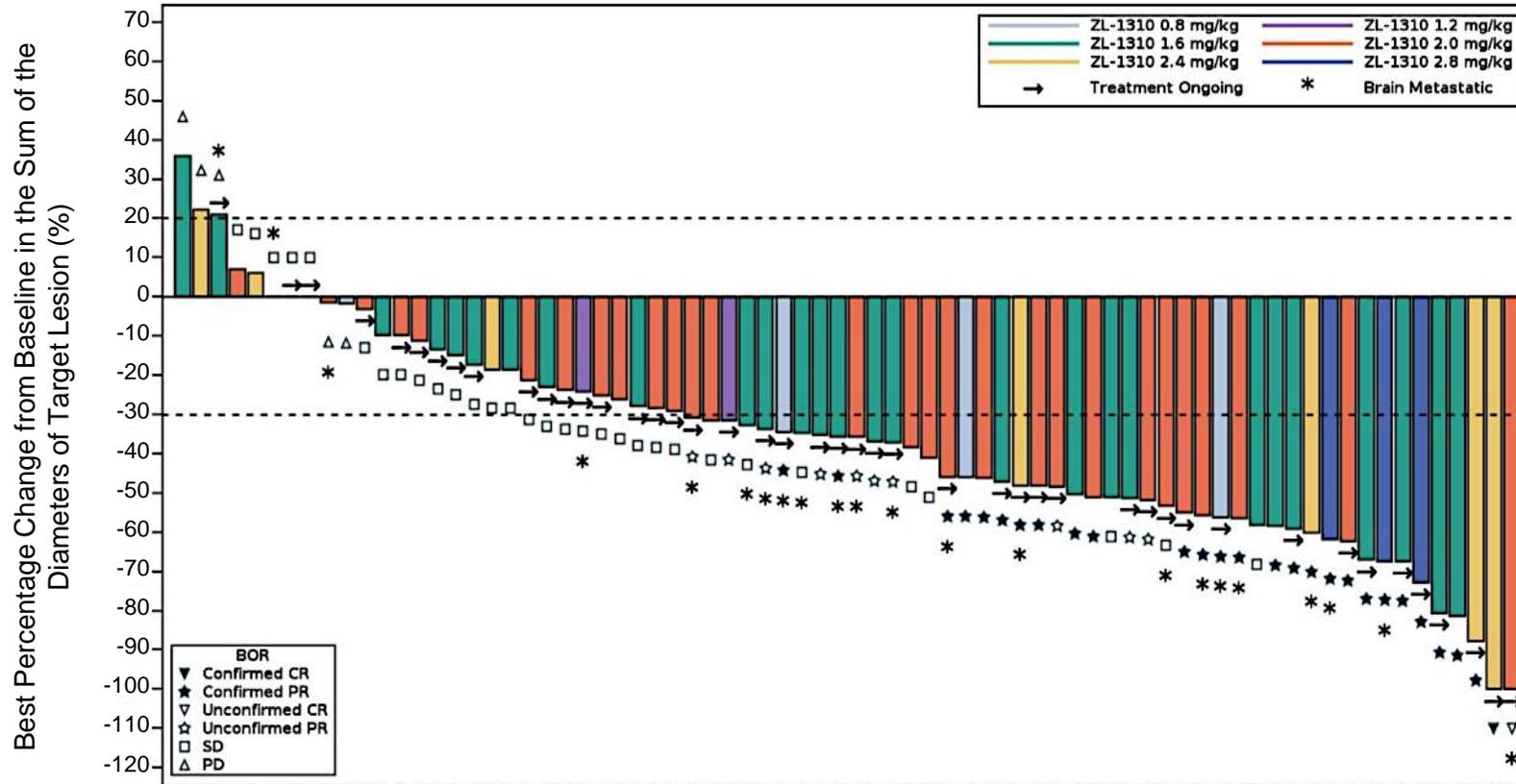
- 1.6 mg/kg in 2L SCLC:
  - **ORR\* of 79%**
  - **DCR of 100%**
- All doses in 2L SCLC:
  - **ORR\* of 67%**
  - **DCR of 97%**

As of data cut-off: Median follow-up time was 3.7 months (95% CI <1, 12.2)

Notes: \*Includes confirmed and unconfirmed responses. (1) Included 1 patient with unconfirmed CR in 2.0 mg/kg cohort and 1 patient with confirmed CR in 2.4 mg/kg cohort; (2) Included 2 patients with confirmed PR in 0.8 mg/kg cohort; 8 patients with confirmed PR and 3 patients with unconfirmed PR in 1.6 mg/kg cohort; 3 patients with confirmed PR and 2 patients with unconfirmed PR in 2.0 mg/kg cohort; and 2 patients with confirmed PR in 2.8 mg/kg cohort; (3) As the study is still ongoing, these responses are pending confirmation at the time of next tumor scan.

# Efficacy - Waterfall Plot

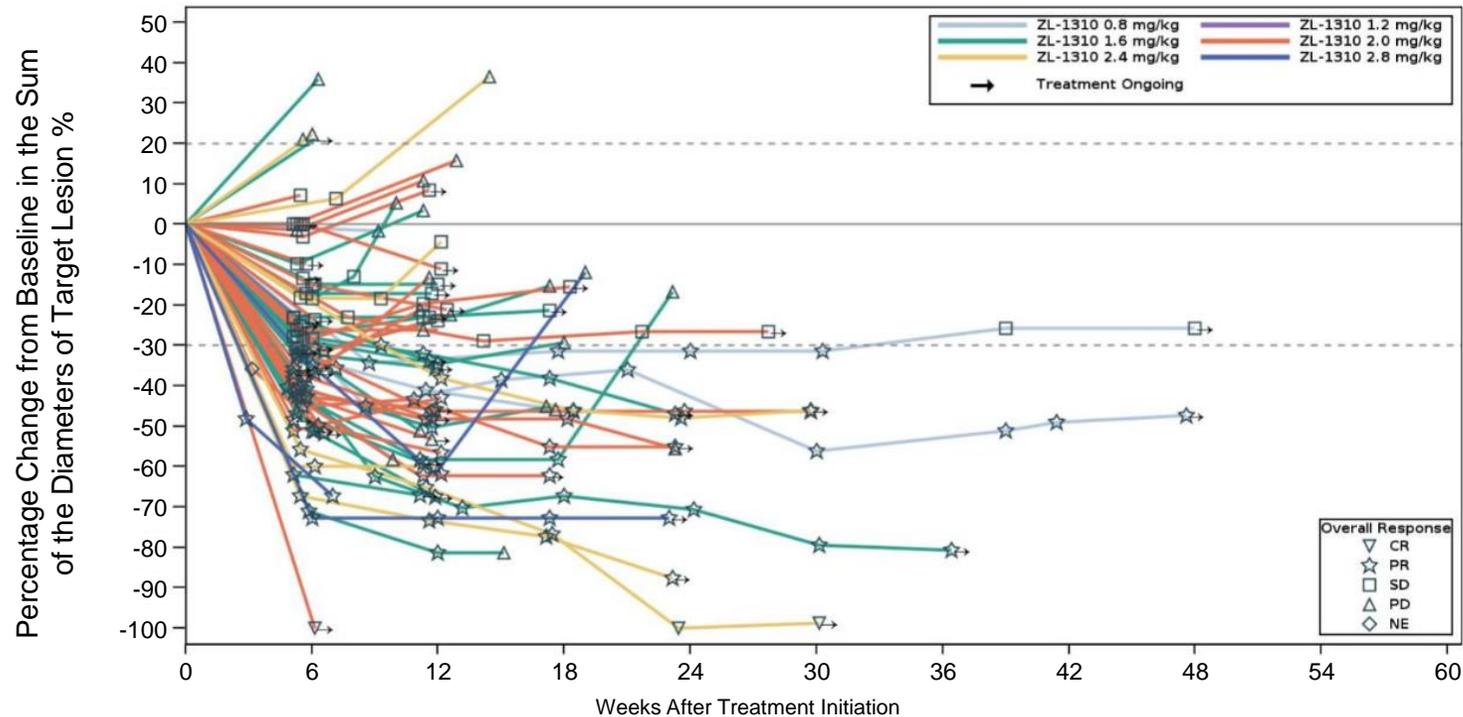
Waterfall Plot of Best Change in Sum of Target Lesions by Dose Levels (N=74)



- Most pts had a decrease in target tumor lesion (89%)
- 55% (17/31) of stable disease patients have tumor reduction and treatment is still ongoing
- Longest patients remaining on study at 48+ weeks

# Efficacy - Spider Plot

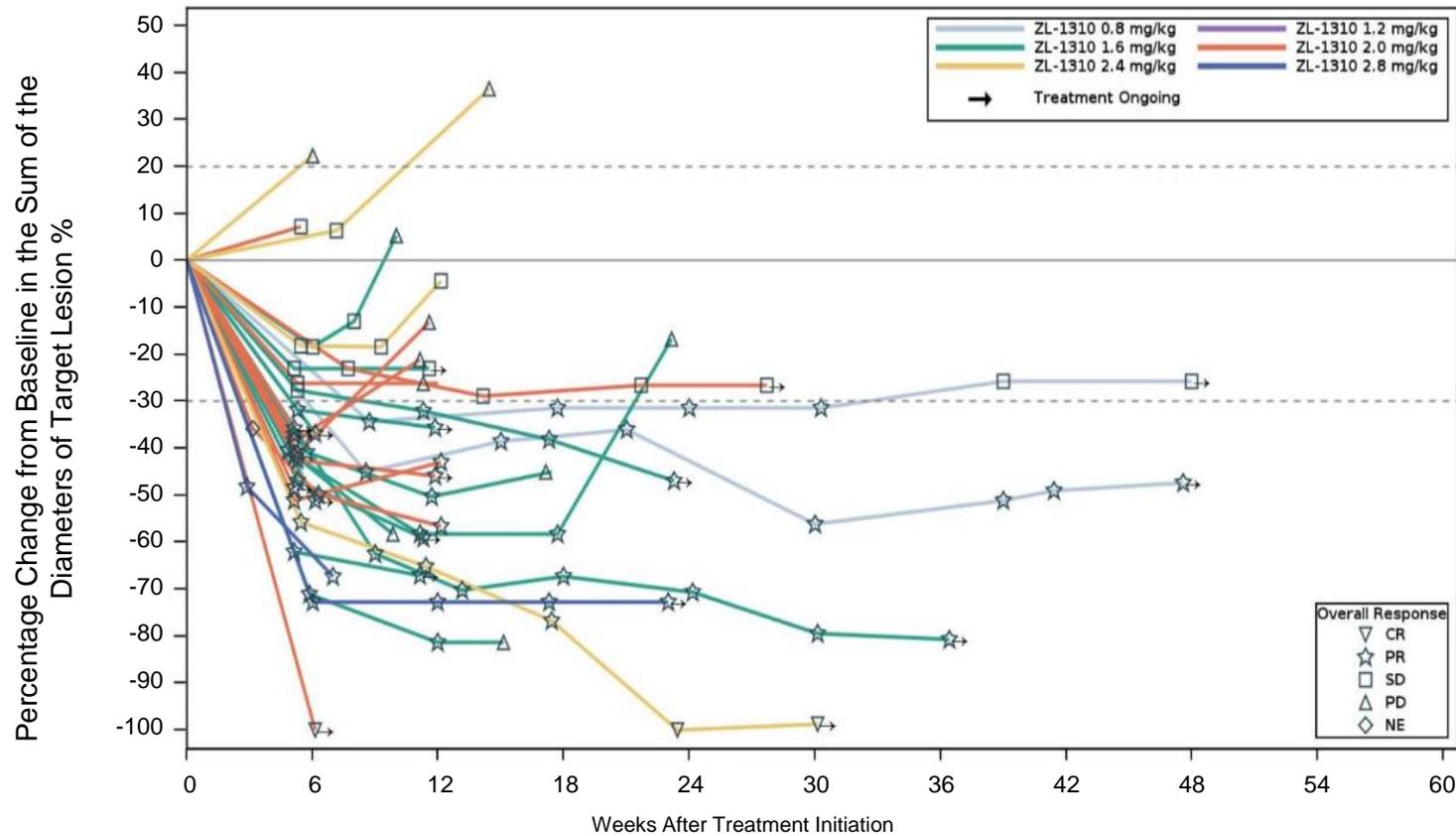
Spider Plot of Sum of Target Lesions over Time by Dose Levels (N=74)



- Large reduction in target lesions seen in majority of patients across doses and lines of therapy
- Majority of patients had tumor reduction by 6 weeks with median time to response of 5.57 weeks

# Efficacy - Spider Plot (Patients with 1 Prior Line)

Spider Plot of Sum of Target Lesions for 1 Prior Line (N=33)



- In 2L SCLC:

- 64% of patients with 1 prior line remain on study
- Longest patient in response has been on study approaching 48 weeks
- Longest patient at 1.6 mg/kg in response has been on study for over 36 weeks

# Efficacy – Patients with Brain Metastases

## Best Overall Response for Patients with Brain Metastases at Study Entry (N=22)

	All Pts w/ Brain Mets (N=22)	Pts w/o prior radiation (N=7)	Pts w/ prior radiation (N=15)
Best Overall Response – n (%)			
CR <sup>1</sup>	1 (5%)	0	1 (7%)
PR <sup>2</sup>	14 (64%)	6 (86%)	8 (53%)
Stable Disease	5 (23%)	0	5 (33%)
Progressive Disease	2 (9%)	1 (14%)	1 (7%)
<b>ORR – n (%)</b>	<b>15 (68%)</b>	<b>6 (86%)</b>	<b>9 (60%)</b>
Confirmed	10 (46%)	5 (71%)	5 (33%)
Pending confirmation <sup>3</sup>	5 (22%)	1 (15%)	4 (27%)

- Pts with brain metastases at baseline (N=22) had an ORR\* of 68%
- Pts with brain metastases without prior radiation had an ORR\* of 86%
- 100% (4/4) pts with brain lesions who either had no prior radiation or received radiation more than 6 months earlier experienced intracranial tumor shrinkage

Notes: \*Includes confirmed and unconfirmed responses. (1) Unconfirmed CR; (2) Included 10 patients with confirmed PR and 4 patients with unconfirmed PR in all patients with brain metastases; among patients without prior radiation, 5 patients with confirmed PR and 1 patient with unconfirmed PR; among patients with prior radiation, 5 patients with confirmed PR and 3 patients with unconfirmed PR; (3) As the study is still ongoing, these responses are pending confirmation at the time of next tumor scan.

# Conclusions

- ZL-1310 demonstrated an acceptable safety profile with low rates of drug withdrawal and low-rates of high-grade adverse events
- ZL-1310 presented encouraging anti-tumor activity in patients with relapsed or recurrent ES-SCLC, including those with brain metastases
- Insufficient follow-up precludes computation of mDOR, but most patients with stable disease had tumor regression and 55% (17/31) of stable disease patients have tumor reduction and treatment is still ongoing
- Responses were especially notable among patients who had undergone one line of prior platinum-based systemic therapy at the 1.6 mg/kg dose
- Based on the Phase 1 trial data, a Phase 3 pivotal trial assessing ZL-1310 in ES-SCLC patients who have progressed during or after platinum-based therapy is planned to start later this year



## Rafael Amado, MD

President, Head of Global  
Research and Development,  
Zai Lab

ZL-1310 (DLL3 ADC) Highlights from ASCO 2025

**Next Steps and Conclusions**

Q&A with Dr. Amado and Dr. Spira

# 2L ES-SCLC Development Strategy

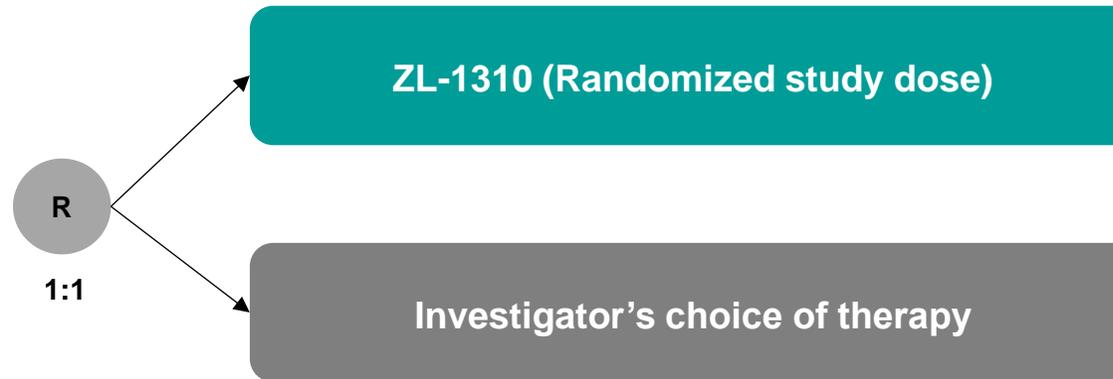
- Dose Optimization in 2L+ SCLC continuing with 1.2 mg/kg and 1.6 mg/kg
- Randomized, registrational trial initiating in 2H'25
  - Primary endpoint: OS, ORR (for accelerated approval)

## Eligible Patients

- ES-SCLC
- Must have progressed following the platinum-based regimen
- Received only 1 line of prior systemic therapy
- At least one measurable lesion
- ECOG 0-1

## Stratification factors

- Brain mets : Yes vs No
- CTFI  $\geq 90$  days: Yes vs No
- Investigator's choice: Topo vs Lurb / Amru



## Primary endpoints

- BICR-ORR
- OS

## Secondary endpoints

- DOR
- PFS, TTR
- Safety
- QoL

# Rapidly Advancing ZL-1310 in SCLC and Other DLL3-Expressing Tumors



## Key Catalysts

### 2L SCLC

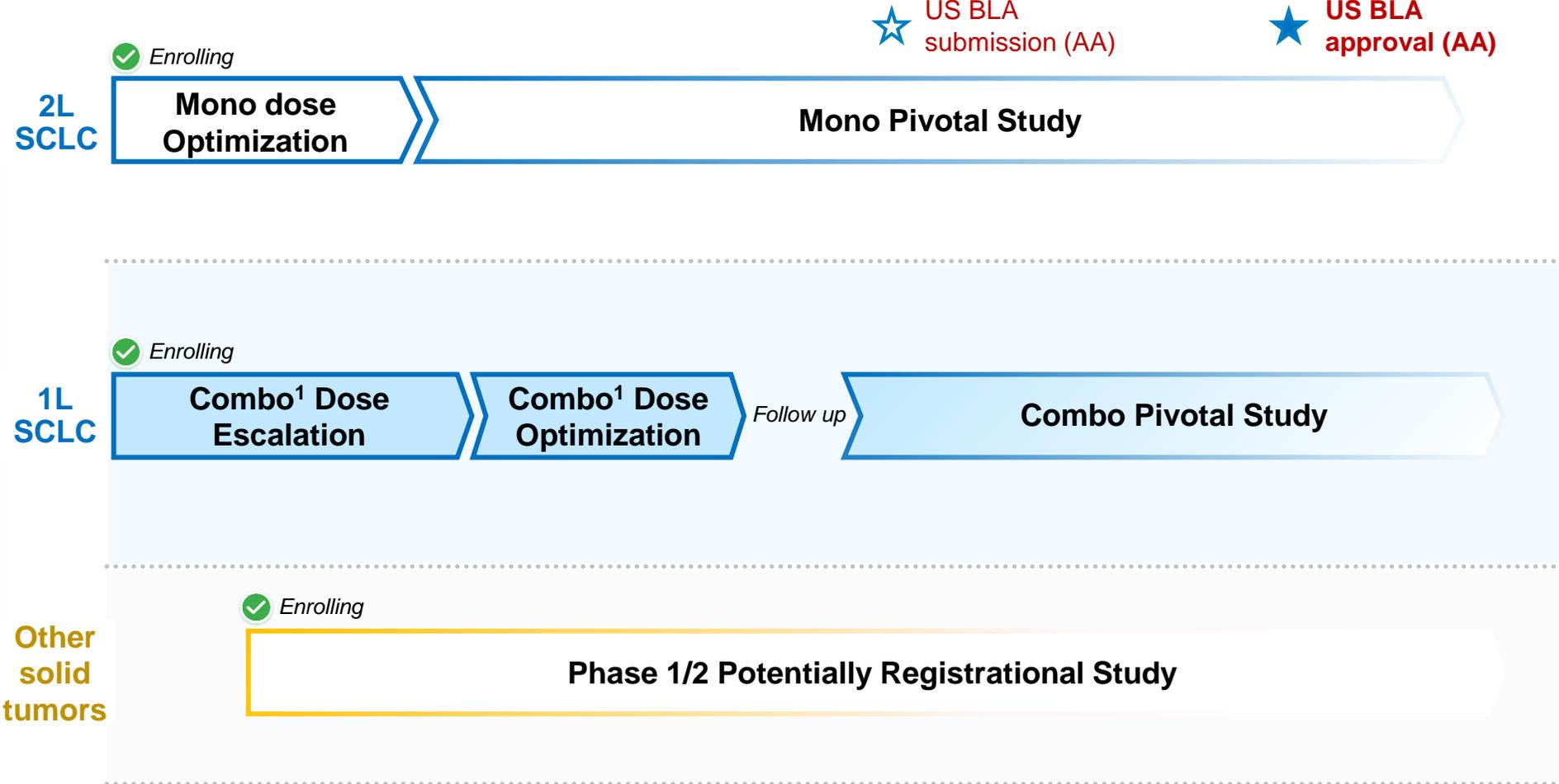
- Initiation of pivotal study in 2H'25

### 1L SCLC

- Data update for ZL-1310 combo by YE'25

### Other DLL3-expressing tumors

- ✓ Ph1/2 study ongoing



Notes: The estimate of development timeline is subject to FDA feedback. (1) Including doublet and triplet; decision will be based on the available data.

# ZL-1310 – Potential First-in-Class and Best-in-Class DLL3 ADC

- **2L+ SCLC** – High confirmed ORR of 68% across all doses in dose escalation (n=28)
- **2L SCLC** – Confirmed and unconfirmed ORR of 67% across all doses (n=33), with 1.6 mg/kg (n=14) demonstrating strongest response rate thus far with ORR of 79%
- **Potential best-in-class safety profile** in doses <2.0 mg/kg (n=50), with Grade ≥3 TRAEs of 6%, no Grade ≥3 ILD and no TRAEs leading to drug discontinuation or death
- **Compelling intracranial activity** for patients with brain metastases of 68% ORR (n=22); 86% ORR (n=6) in patients with brain metastases without prior radiation
- **ZL-1310's safety and efficacy profile remains highly competitive in 2L SCLC, and advancing into 1L ES-SCLC as combination therapy**
- **Other NECs** – Global Phase 1/2 study ongoing

***Next Steps: Randomized, pivotal trial in 2L SCLC to initiate in H2 2025 with 1.6 mg/kg\****



**Rafael Amado, MD**

President, Head of Global  
Research and Development,  
Zai Lab



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

Co-Director, Virginia Cancer  
Specialists Research Institute

ZL-1310 (DLL3 ADC) Highlights from ASCO 2025

Next Steps and Conclusions

**Q&A with Dr. Amado and Dr. Spira**