ESMO 2026

Zoci (ZL-1310): 有望成为小细胞肺癌和神经内分泌癌治疗的基石药物

2026年10月

NASDAQ:ZLAB | HKEX:9688

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前瞻性声明

本演示材料包含前瞻性陈述，包括与以下方面相关的陈述：我们的策略和计划；我们的业务、商业化产品及管线项目的潜力和预期；特别是 zoci（ZL-1310），我们的目标、目的和重点事项，以及我们基于增长战略的预期（包括我们对商业化产品和上市以及 zoci 等临床阶段产品的预期）；我们项目的峰值销售潜力；资本配置与投资策略；临床开发计划和相关临床研究，包括临床研究的计划启动、设计和数量，以及我们与合作伙伴的联合治疗方案的计划；临床研究数据、数据解读和发布的预期时间与结果；注册相关的讨论、提交、申请、获批及时间线，包括新药临床试验申请（IND）的预期时间、我们首个生物制品许可申请（BLA）的潜在提交以及潜在的全球批准；我们及我们合作伙伴的产品和候选产品的潜在裨益、安全性和有效性；投资、合作及业务拓展活动的预期收益和潜力；我们商业化产品和候选产品的潜在市场机会及预估的可及市场，包括预估患者人群；以及我们未来的财务和经营业绩。除对过往事实的陈述外，本演示材料中包含的所有陈述均为前瞻性陈述，可以通过诸如“旨在”、“预计”、“认为”、“有可能”、“估计”、“预期”、“预测”、“目标”、“打算”、“可能”、“计划”、“可能的”、“潜在”、“将”、“将会”等词汇及其他类似表述加以识别。该等陈述构成美国联邦证券法所定义的前瞻性陈述。前瞻性陈述并非对未来表现的担保或保证，因为预测未来结果存在固有困难。

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今日讲者与议程

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介绍

Rafael Amado，医学博士

Zoci：2026 ESMO 亮点 – 一线小细胞肺癌

Pedro Rocha, 医学博士，哲学博士，理学硕士

总结和问答

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披露信息

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持续拓展全球肿瘤与免疫管线，数据读出保持稳定节奏

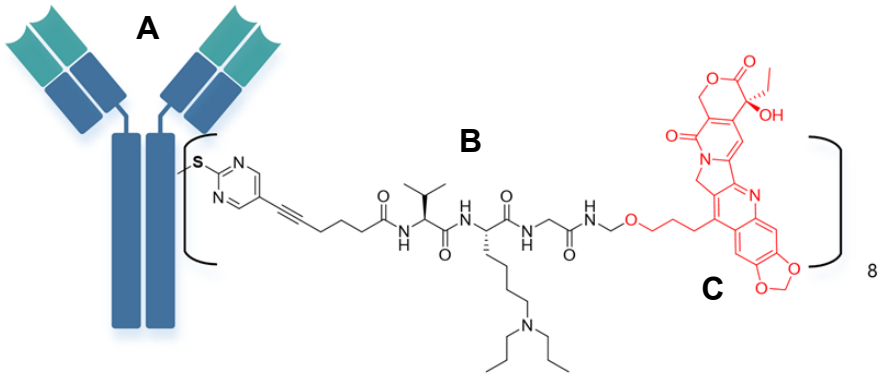
	项目（靶点）		适应证	IND支持阶段	I期	概念验证	注册性研究/III期	当前状态/下一次更新
肿瘤	**Zoci** (DLL3 ADC)	Zoci	2L+ 小细胞肺癌				●	**数据**（中期分析）：2027年下半年
		Zoci + PD-(L)1	1L 小细胞肺癌			●		**数据**已于ESMO大会公布；III 期研究计划中
		Zoci + tarlatamab (TCE)[1] ± PD-L1	1L+ 小细胞肺癌		●			Ib 期研究正在进行中
		Zoci + obrixtamig (TCE)[2] ± PD-L1	小细胞肺癌及肺外神经内分泌癌		●			Ib/II 期研究将于2026年下半年启动
		Zoci	肺外神经内分泌癌				●	**数据**（注册性研究）：2027年上半年
	ZL-6201 (LRRC15 ADC)	ZL-6201	肉瘤及其他肿瘤			●		**数据**（概念验证）：2027年上半年
	ZL-1222 (PD-1/IL-12)	ZL-1222	实体瘤	●				I 期研究将于2027年启动
	ZL-1311 (MUC17/CD3 TCE)	ZL-1311	实体瘤	●				I 期研究将于2027年上半年启动
	ZL-6202 (未披露)	ZL-6202	实体瘤	候选药物遴选				
	ZL-1223 (未披露)	ZL-1223	实体瘤	候选药物遴选				
免疫	**ZL-1503** (IL-13/IL-31Rα)	ZL-1503	中重度特应性皮炎			●		**数据**（健康志愿者SAD）：2026年第四季度 **数据**（特应性皮炎患者MAD）：2027年上半年
	ZL-1505 (未披露)	ZL-1505	免疫性疾病	候选药物遴选				

注：SAD：单次递增剂量；MAD：多次递增剂量。（1）安进负责申办并主导全球Ib/II期研究；再鼎医药提供研究药物。（2）勃林格殷格翰负责申办并主导全球Ib/II期研究；再鼎医药提供研究药物。

Zoci：兼具强效抗肿瘤活性与良好耐受性的新一代ADC

Zoci基于TMALIN®平台构建，实现强效、精准的肿瘤杀伤[1]

ZL-1310的结构与作用机制



A：人源化抗DLL3 IgG1单克隆抗体
B：可裂解的三肽连接子
C：喜树碱衍生物载荷C24

Zocilurtatug pelitecan（简称zoci）是一款靶向DLL3的新型ADC。DLL3是一种神经内分泌肿瘤特异性抗原，在小细胞肺癌中呈高表达[2-4]，并已被验证为具有治疗价值的靶点。

关键特性

DAR＝8
向靶细胞高效递送载荷

肿瘤微环境特异性释放
通过肿瘤微环境可激活连接子减少全身毒性，提升耐受性

强效旁观者杀伤效应
Topo-1抑制剂载荷C24可增强抗肿瘤作用，包括对异质性肿瘤的杀伤

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

五大特性使zoci有望成为小细胞肺癌和神经内分泌癌治疗的基石ADC

差异化的临床特征、正在开展的全球III期研究，以及覆盖小细胞肺癌和神经内分泌癌的广泛开发计划

01

高缓解率

02

持久缓解

03

潜在同类最佳的安全性

04

强劲的颅内抗肿瘤活性

05

全球领先的临床开发进展

强劲疗效 • 良好耐受性 • 颅内抗肿瘤活性 • 全球开发

DLL3 ADC

Zoci (ZL-1310)

ESMO 2026 Data Update

Pedro Rocha, MD, PhD, MSc
Vall d'Hebron University Hospital

ZL-1310 (DLL3 ADC) plus atezolizumab ± carboplatin in Extensive-stage Small Cell Lung Cancer

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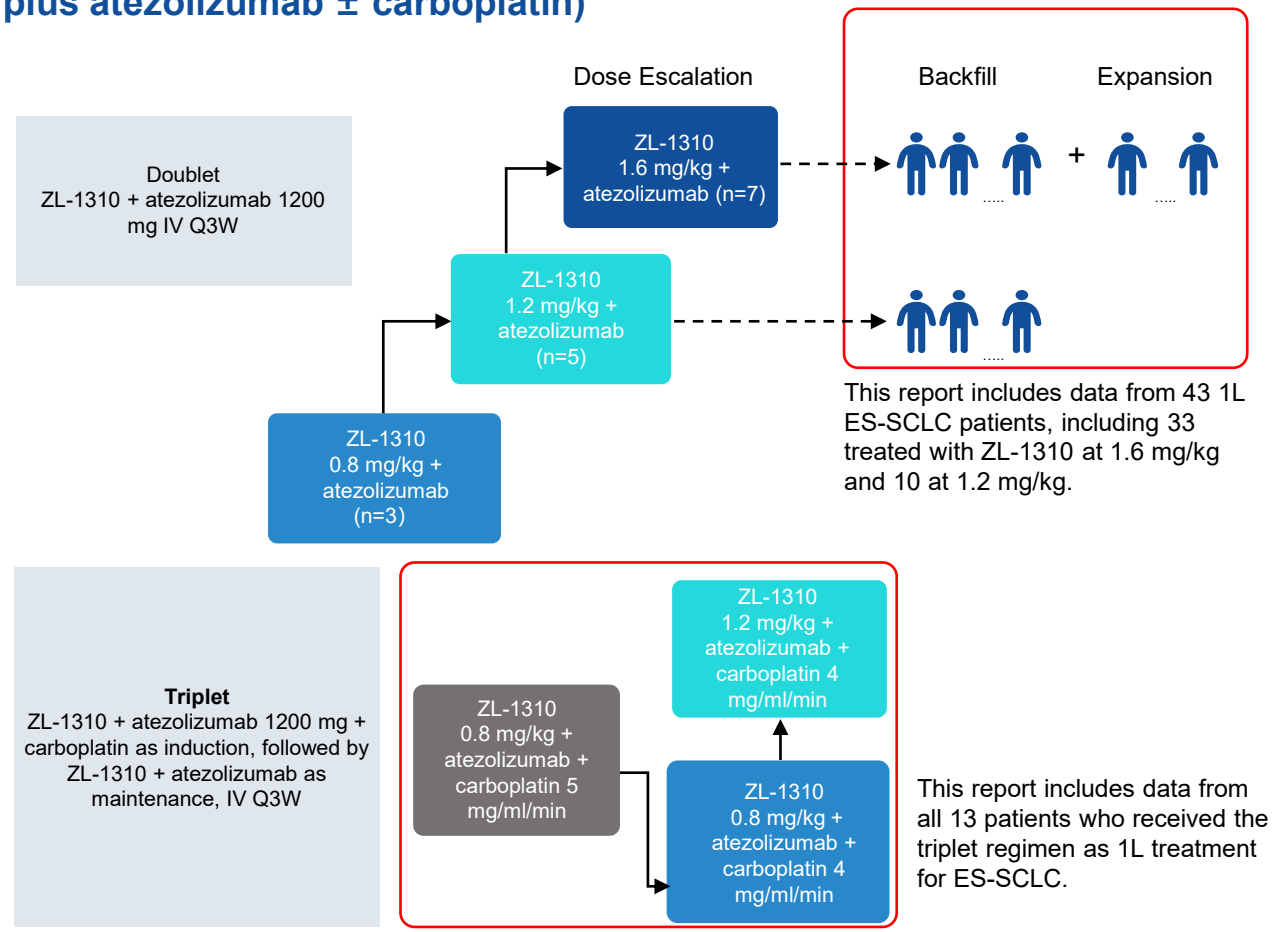
Study Overview

- Phase I, open-label, dose-escalation and expansion study of ZL-1310 as monotherapy and in combination with atezolizumab, with (triplet) or without (doublet) carboplatin in ES-SCLC (NCT06179069).
- Efficacy and safety reported for 1L patients who had the opportunity of at least 12-week follow-up with data cutoff date of Sept 9, 2026.

ZL-1310-001 Study Schema (ZL-1310 plus atezolizumab ± carboplatin)

- **Patient population**
- **Doublet:**
  - **Dose escalation:** relapsed / refractory ES-SCLC ≤2 prior lines of therapy.
  - **Backfill:** Newly diagnosed ES-SCLC (1L) or ES-SCLC completed standard 1L induction therapy and had not progressed (1L maintenance).
  - **Expansion:** Newly diagnosed ES-SCLC (1L)
- **Triplet:** Newly diagnosed ES-SCLC (1L)
- Asymptomatic brain metastasis (treated or untreated) allowed
- Prior DLL3-targeted therapy allowed
- ECOG Performance Status 0-1



Q3W: once every 3 weeks; PS: Performance Status; RECIST v1.1: Response Evaluation Criteria in Solid Tumors version 1.1

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Baseline Characteristics for 1L Patients

ZL-1310 + atezolizumab doublet:

- At ZL-1310 1.6 mg/kg, 33 patients were enrolled; the first 15 in the back fill cohort had the opportunity for ≥6 months of follow-up, with a median follow-up of 10.0 months.
- At ZL-1310 1.2 mg/kg, 10 patients were enrolled; all had ≥6 months follow-up, with a median follow-up of 12.6 months.

ZL-1310 + atezolizumab + carboplatin triplet:

- In the dose-escalation triplet cohorts, 13 patients were enrolled, with median follow-up of 11.8 months.

Demographics and Baseline Characteristics for 1L Patients

	ZL-1310 + atezolizumab doublet			ZL-1310 + atezolizumab + carboplatin triplet			
	Dose Level		Total	Dose Level			Total
	ZL-1310			ZL-1310			
				Carbo AUC5	Carbo AUC4		
	1.2 mg/kg (n=10)	1.6 mg/kg (n=33)	Total (n=43)	0.8 mg/kg (n=4)	0.8 mg/kg (n=3)	1.2 mg/kg (n=6)	Total (n=13)
Male, n (%)	8 (80.0)	26 (78.8)	34 (79.1)	3 (75.0)	3 (100)	4 (66.7)	10 (76.9)
Age, median (range), years	62 (51, 75)	63 (46, 75)	63 (46, 75)	61 (58, 66)	69 (66, 69)	68 (59, 75)	66 (58, 75)
ECOG PS = 1, n (%)	7 (70.0)	25 (75.8)	32 (74.4)	3 (75.0)	3 (100)	5 (83.3)	11 (84.6)
Race, n (%)							
Asian	10 (100)	30 (90.9)	40 (93.0)	3 (75.0)	2 (66.7)	2 (33.3)	7 (53.8)
White	0	3 (9.1)	3 (7.0)	0	1 (33.3)	4 (66.7)	5 (38.5)
Brain Metastasis-Yes, n (%)	2 (20.0)	6 (18.2)	8 (18.6)	1 (25.0)	0	2 (33.3)	3 (23.1)
Stage IV disease at initial diagnosis, n (%)	8 (80.0)	25 (75.8)	33 (76.7)	3 (75.0)	2 (66.7)	5 (83.3)	10 (76.9)

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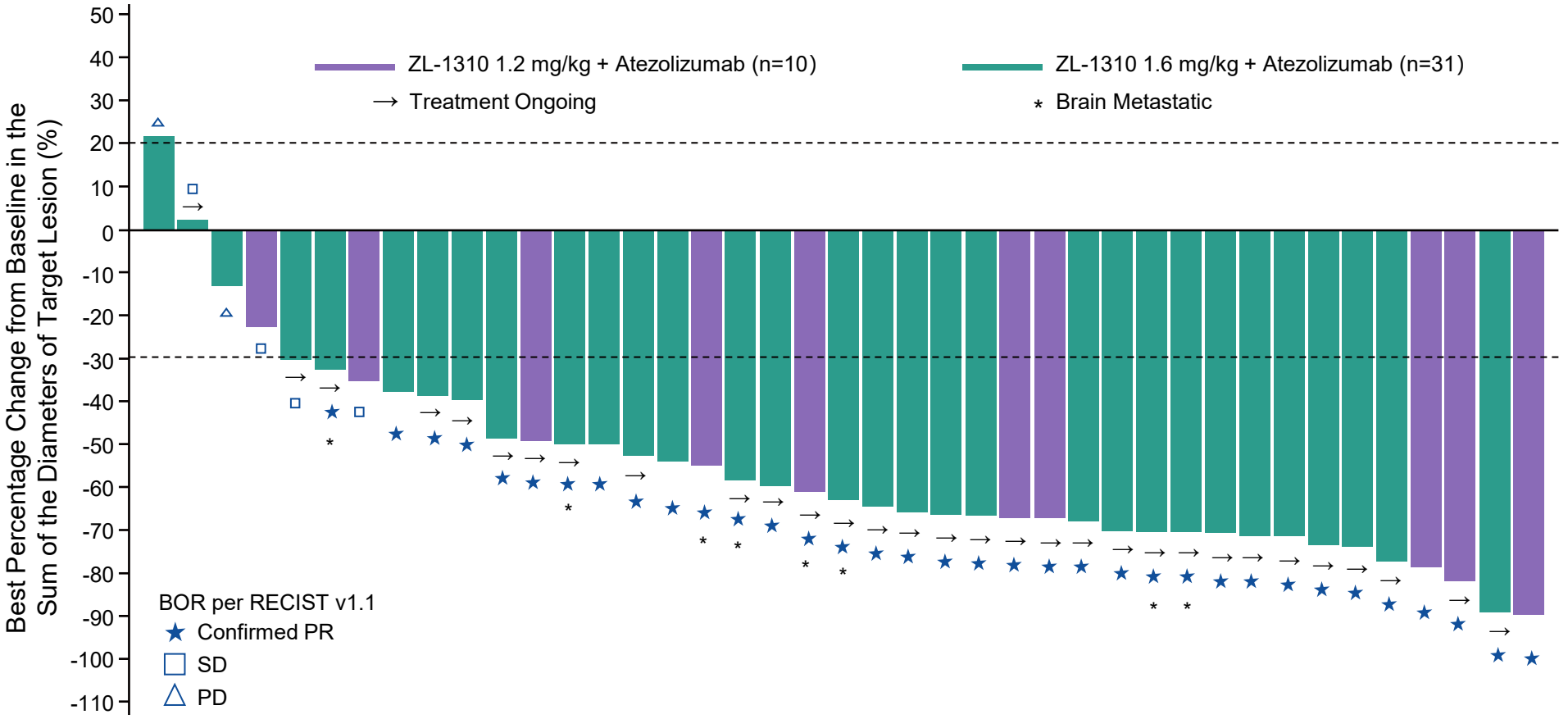
Results: Target Tumor Reduction of Doublet in 1L

- High overall response rates were observed in patients receiving ZL-1310 + atezolizumab as 1L therapy (ORR for all dose level: 81.4%).

Target Tumor Reduction per RECIST v1.1 by Investigator Assessment



Tabe 2. Best Overall Response per RECIST v1.1 by Investigator Assessment

Tumor response	ZL-1310 1.2 mg/kg + Atezo (N=10)	ZL-1310 1.6 mg/kg + Atezo (N=33)
Best overall response, n (%)		
CR	0	0
PR	8 (80.0)	27 (81.8)
SD	2 (20.0)	2 (6.1)
PD	0	2 (6.1)
cORR, % (95% CI)	80.0 (44.4, 97.5)	81.8 (64.5, 93.0)

* Patients without target lesions at baseline or evaluable post-baseline tumor assessments were not shown. As of the DCO, two patients reached EOT without disease progression before an evaluable post-baseline assessment was obtained.

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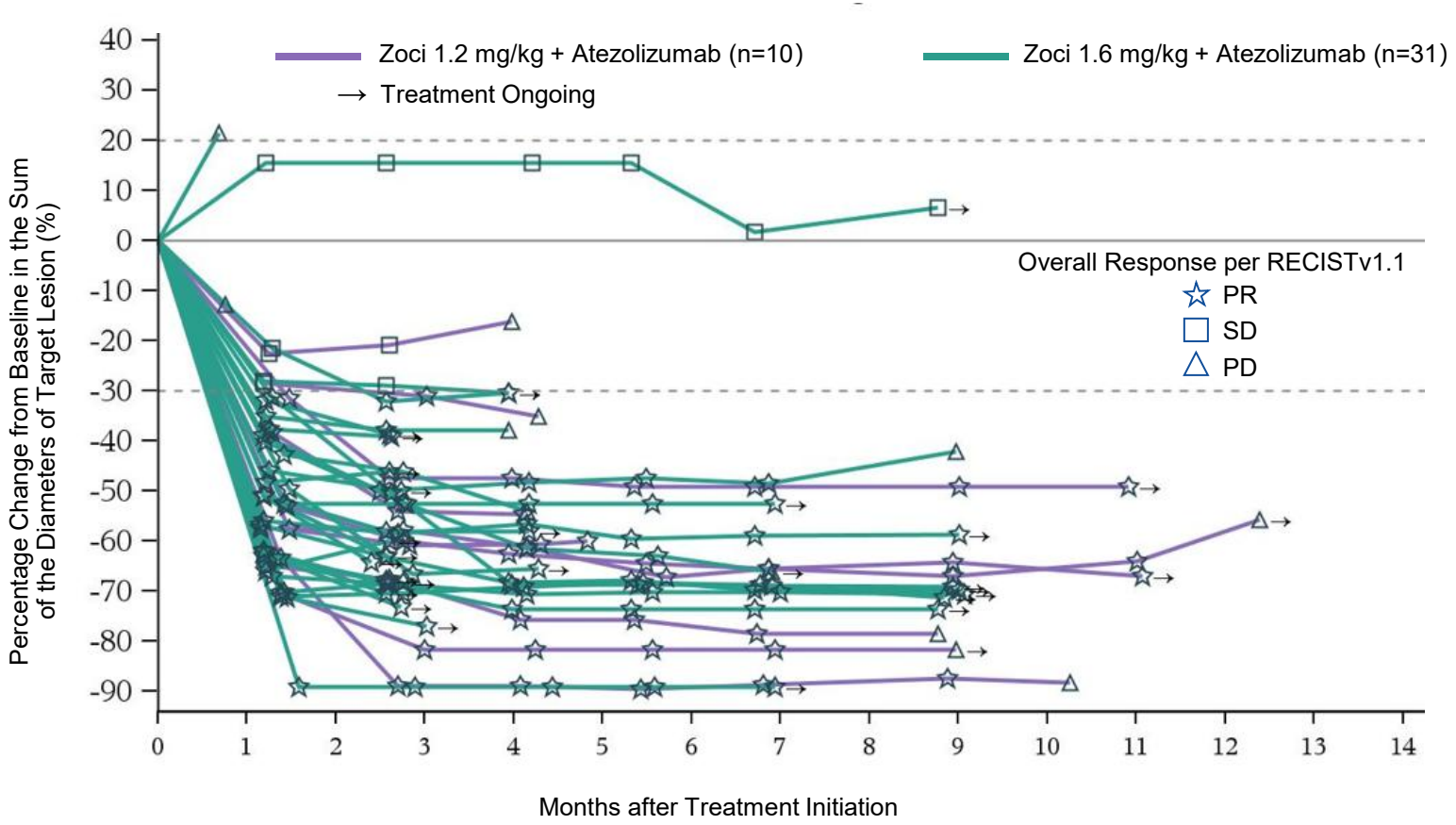
Results: Durability of Tumor Reduction with Doublet

- Responses occurred rapidly: 34/35 (97.1%) responders achieving their response at the first post-baseline tumor assessment.
- The responses were durable.
  - In the 10 patients receiving ZL-1310 1.2 mg/kg + atezolizumab as 1L, mDoR was 8.3 (4.0, NA) months.
  - In the first 15 patients receiving ZL-1310 1.6 mg/kg + atezolizumab as 1L, mDoR is not reached after a median follow-up of 10.0 months.

Durable Tumor Reduction Observed in Doublet Cohorts



All 33 patients on 1.6 mg/kg doublet

81.9% 6-month PFS rate

75.8% Of patients still on treatment as of DCO (25/33)

In the first 15 patients of 1.6mg/kg doublet in 1L: (median follow-up: 10 mo)

66.7% Have not yet experienced disease progression or death at DCO

NR Median PFS

NR = not reached

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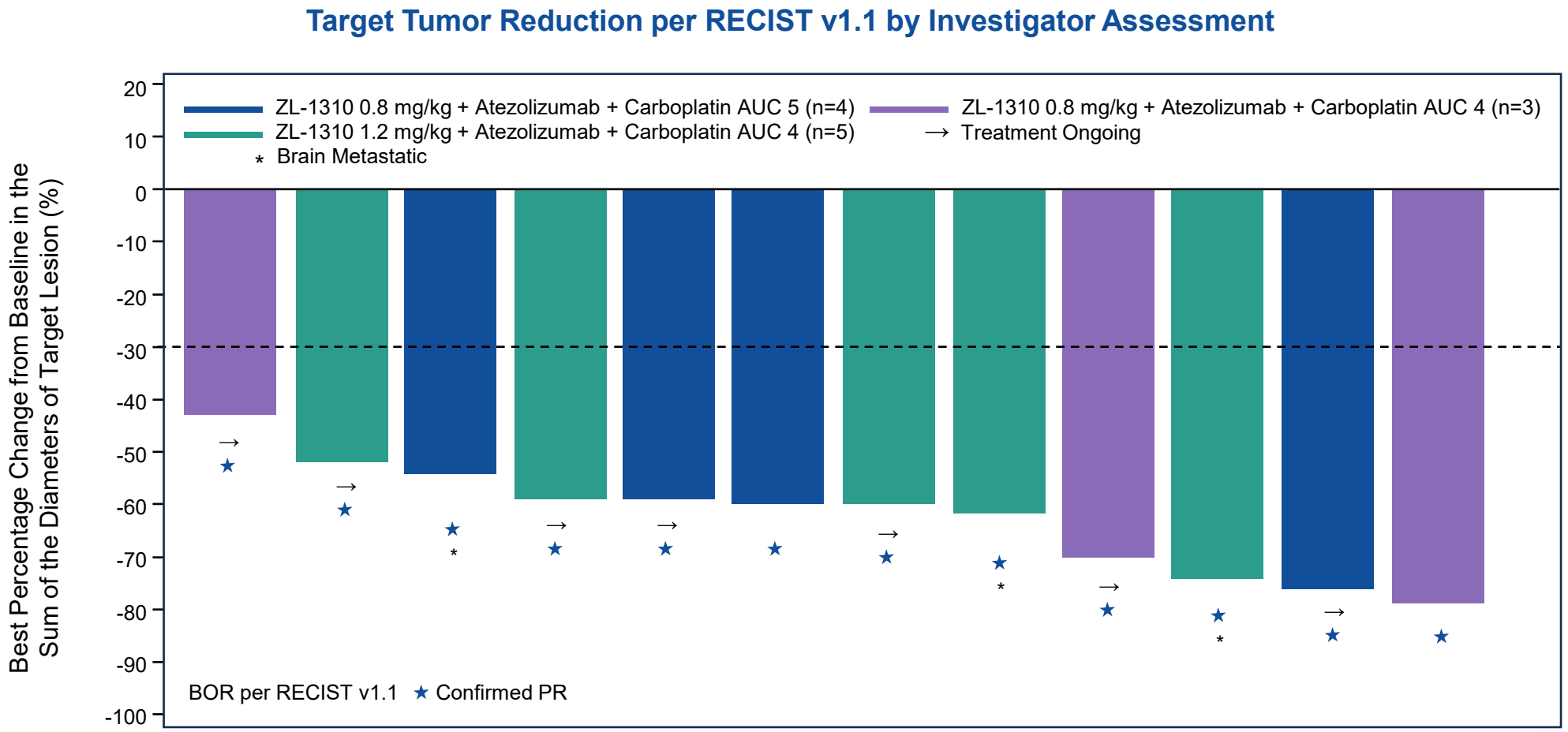
Results: Target Tumor Reduction of Triplet in 1L

- Patients receiving ZL-1310 in combination with atezolizumab and carboplatin as 1L therapy demonstrated a high overall response rate (ORR) of 92.3%.



* Patients without target lesions at baseline or evaluable post-baseline tumor assessments were not shown. As of the DCO, one patient in triplet cohort reached EOT without disease progression before an evaluable post-baseline assessment.

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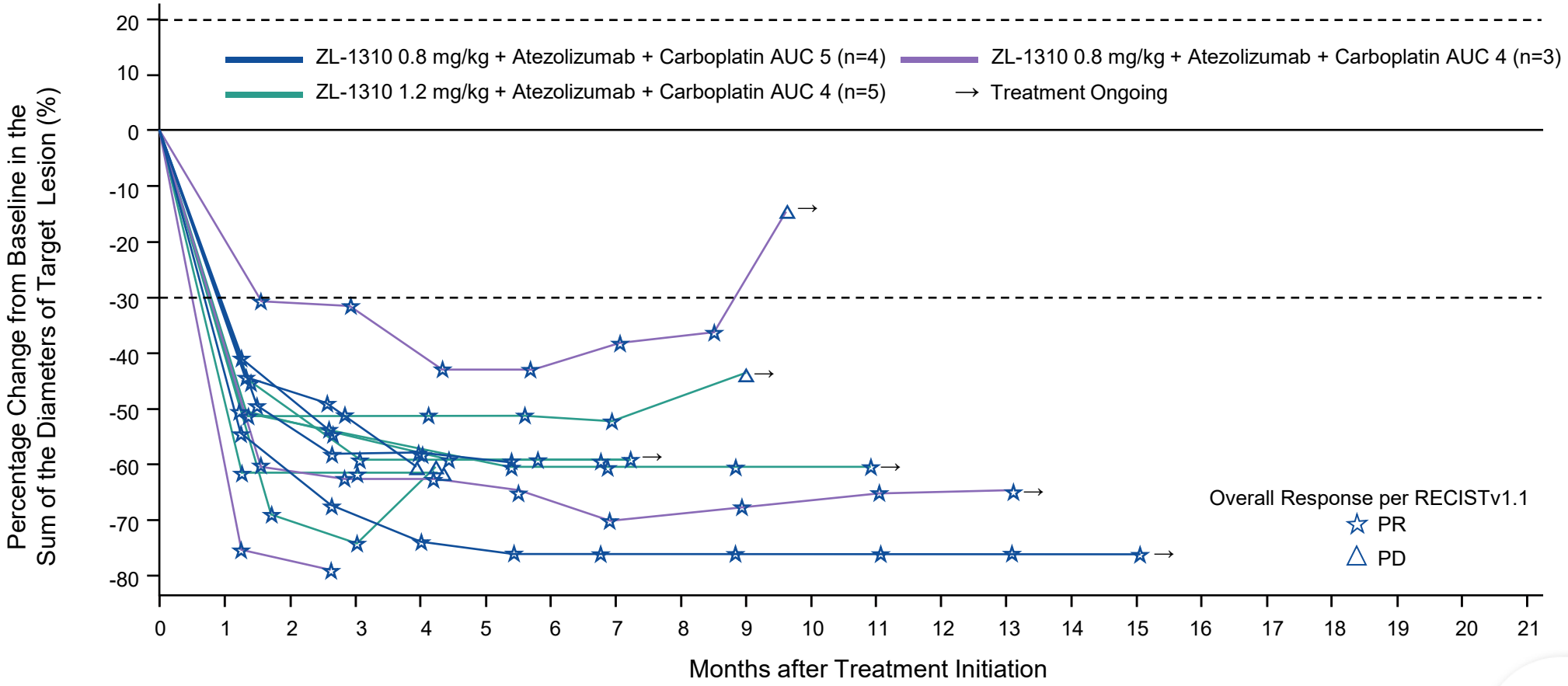
Results: Durability of Tumor Reduction with Triplet

- Patients receiving ZL-1310 in combination with atezolizumab and carboplatin as 1L therapy demonstrated a high overall response rate (ORR) of 92.3%.
- mPFS is 8.4 months (95% CI 3.7, NA) and mDoR is 7.7 months (2.6, NA).

Durable Tumor Reduction Observed in Triplet Cohort



Results: Safety of Doublet as 1L Therapy

ZL-1310 plus atezolizumab is well tolerated.

- No DLTs were observed in the dose escalation phase.
- The majority of AEs were Grade 1 or 2, and non-serious.
- Grade ≥3 AEs related to ZL-1310 occurred in 7/43 (16.3%) of patients, and SAEs related to ZL-1310 occurred in 5/43 (11.6%) of patients.
- AE rate related to ZL-1310 that led to dose reduction (4.7%, 2/43) or discontinuation (1/43, 2.3%) was low.
- No treatment-related deaths were reported.

Summary of Adverse Events - Doublet Combination Safety Analysis Set

AEs, n (%)	ZL-1310 1.2 mg/kg + Atezolizumab (N=10)	ZL-1310 1.6 mg/kg + Atezolizumab (N=33)	Total (N=43)
Any	10 (100)	32 (97.0)	42 (97.7)
Related to ZL-1310	10 (100)	31 (93.9)	41 (95.3)
Serious	4 (40.0)	6 (18.2)	10 (23.3)
Related to ZL-1310	2 (20.0)	3 (9.1)	5 (11.6)
Grade ≥ 3	5 (50.0)	7 (21.2)	12 (27.9)
Related to ZL-1310	4 (40.0)	3 (9.1)	7 (16.3)
Leading to ZL-1310 Drug Interruption (1)	5 (50.0)	9 (27.3)	14 (32.6)
Related to ZL-1310	4 (40.0)	5 (15.2)	9 (20.9)
Leading to ZL-1310 Dose Reduction	0	2 (6.1)	2 (4.7)
Related to ZL-1310	0	2 (6.1)	2 (4.7)
Leading to ZL-1310 Drug Discontinuation	1 (10.0)	0	1 (2.3)
Related to ZL-1310	1 (10.0)	0	1 (2.3)

* As dose expansion of ZL-1310 + atezolizumab was ongoing at the data cutoff, safety data remain preliminary and subject to ongoing data cleaning. (1) Drug interruption includes infusion interruption or treatment delay compared with the scheduled date due to AE.

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Results: Safety of Triplet as 1L Therapy

Compared with the doublet, the triplet was associated with increased hematologic toxicity, more frequent Grade ≥3 AEs, and a higher rate of dose interruptions. Although MTD was not met, the ZL-1310 dose was not escalated above 1.2 mg/kg.

- A single DLT, Grade 4 thrombocytopenia, was observed in ZL-1310 0.8 mg/kg + Atezolizumab + Carboplatin AUC 5. No DLTs occurred in the ZL-1310 + Atezolizumab +Carboplatin AUC4 cohorts.
- Grade ≥3 AEs related to ZL-1310 occurred in 7/13 (53.8%) of participants, and SAEs related to ZL-1310 occurred in 3/13 (23.1%).
- One patient from ZL-1310 1.2 mg/kg + Atezolizumab + Carboplatin AUC 4 cohort had over-dose of Carboplatin and treatment-related death due to a G5 Sepsis.

Summary of Adverse Events - Triplet Combination Safety Analysis Set

AEs, n (%)	ZL-1310 0.8 mg/kg + Atezolizumab + Carboplatin AUC 5 (N=4)	ZL-1310 0.8 mg/kg + Atezolizumab + Carboplatin AUC 4 (N=3)	ZL-1310 1.2 mg/kg + Atezolizumab + Carboplatin AUC 4 (N=6)	Total (N=13)
Any	4 (100)	3 (100)	6 (100)	13 (100)
Related to ZL-1310	3 (75.0)	2 (66.7)	5 (83.3)	10 (76.9)
Serious	2 (50.0)	0	5 (83.3)	7 (53.8)
Related to ZL-1310	1 (25.0)	0	2 (33.3)	3 (23.1)
Grade ≥ 3	3 (75.0)	1 (33.3)	6 (100)	10 (76.9)
Related to ZL-1310	2 (50.0)	1 (33.3)	4 (66.7)	7 (53.8)
Leading to ZL-1310 Drug Interruption[1]	4 (100)	3 (100)	4 (66.7)	11 (84.6)
Related to ZL-1310	3 (75.0)	2 (66.7)	4 (66.7)	9 (69.2)
Leading to ZL-1310 Dose Reduction	0	0	1 (16.7)	1 (7.7)
Related to ZL-1310	0	0	1 (16.7)	1 (7.7)
Leading to ZL-1310 Drug Discontinuation	0	0	1 (16.7)	1 (7.7)
Related to ZL-1310	0	0	1 (16.7)	1 (7.7)

(1) Drug interruption includes infusion interruption or treatment delay compared with the scheduled date due to AE.

Common AEs related to ZL-1310 and ILD/pneumonitis

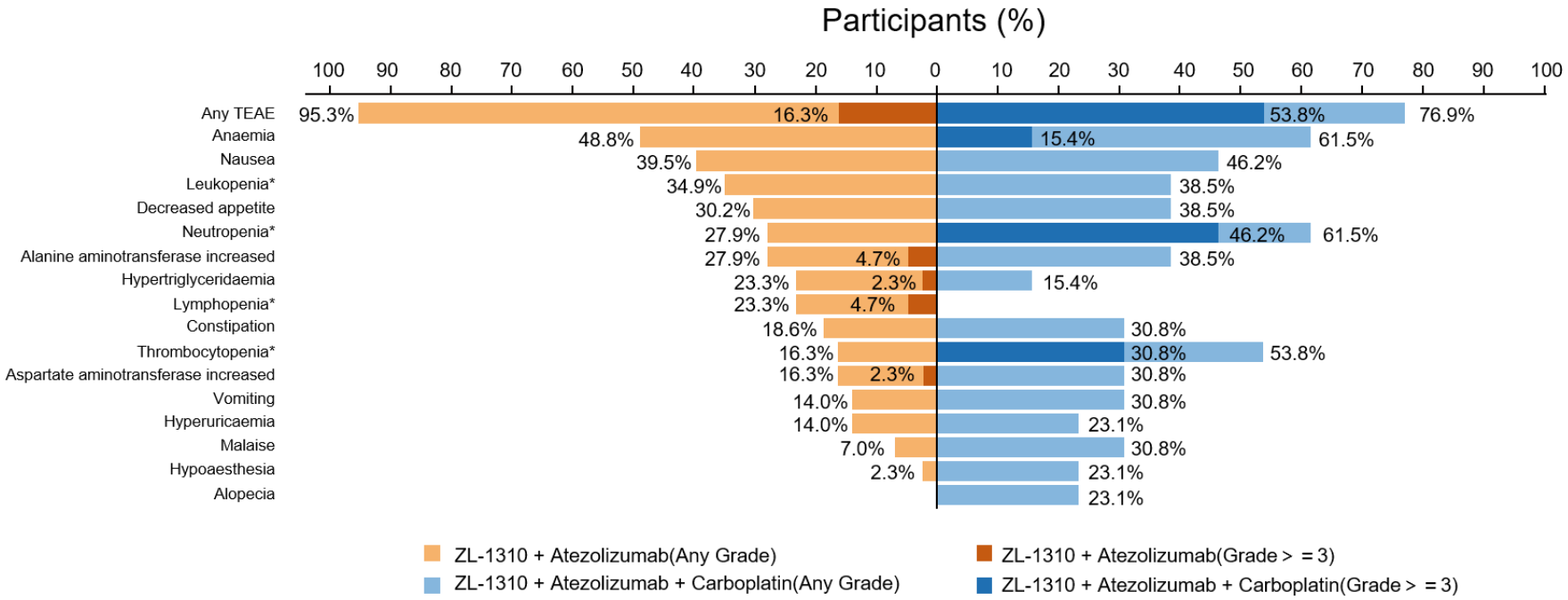
Common ZL-1310 Related AE:

- Doublet: The most common AEs related to ZL-1310 of all grades (≥20%) were anaemia (48.8%), nausea (39.5%), leukopenia* (34.9%), decreased appetite (30.2%), ALT increased, neutropenia* (27.9% each), hypertriglyceridaemia and lymphopenia* (23.3% each)
- Triplet: The most common AEs related to ZL-1310 of all grades (≥20%) were anaemia and neutropenia* (61.5% each), thrombocytopenia* (53.8%), nausea (46.2%), ALT increased, decreased appetite, and leukopenia* (38.5% each), AST increased, constipation, malaise, and vomiting (30.8% each), and alopecia, hyperuricaemia, and hypoaesthesia (23.1% each).

ILD / pneumonitis

- ILD / pneumonitis was low in both regimens: 2/43 (4.7%) in doublet, and 2/13 (15.4%) in triplet, all Grade 1. Only one was reported so far in patients receiving ZL-1310 1.6 mg/kg and atezolizumab as 1L treatment (1/33, 3.0%).

Common TRAEs related to ZL-1310 by grade (≥20%)



Leukopenia* includes AEs coded as Leukopenia and White blood cell count decreased. Neutropenia* includes AEs coded as Neutropenia and Neutrophil count decreased. Lymphopenia* includes AEs coded as Lymphocyte count decreased. Thrombocytopenia* includes AEs coded as Platelet count decreased and Thrombocytopenia.

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Conclusion

- ZL-1310 1.6 mg/kg and atezolizumab doublet combination demonstrated high response rate (81.8%) and durable response as 1L treatment in ES-SCLC (median PFS for the first 15 patients who had 10-month follow-up not yet obtained).
- ZL-1310 1.6 mg/kg and atezolizumab doublet combination is well tolerated. The overall AE rate, Grade 3 and above AE rate, SAE rate with this regimen is not higher than that of ZL-1310 1.6 mg/kg monotherapy as previously reported. Only a G1 ILD / pneumonitis was reported so far in patients receiving ZL-1310 1.6 mg/kg and atezolizumab as 1L treatment (1/33, 3.0%).
- ZL-1310 1.6 mg/kg and atezolizumab doublet combination has more favorable risk / benefit profile compared to ZL-1310 + atezolizumab + carboplatin triplet regimen.
- A Phase III randomized 1L study will be started to further evaluate the combination regimen in ES-SCLC (NCT07796100).

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Summary

Rafael Amado, MD
President, Head of Global R&D

一线小细胞肺癌治疗格局持续演进，zoci战略优势地位凸显

1 当前标准治疗

免疫治疗 ＋ 铂类/依托泊苷 ± 芦比替定维持治疗

诱导治疗
免疫治疗＋铂类/依托泊苷
（4个周期）

维持治疗
免疫治疗

免疫治疗 ＋ 铂类/依托泊苷

＋芦比替定＋免疫治疗维持
用于符合条件且疾病未进展的患者

已发表的研究基准数据[1]

免疫治疗联合化疗（IMpower133/CASPIAN）：
ORR：60%–68%
mPFS：5.1–5.2个月
mOS：12.3–12.9个月
3/4级不良事件：约57%–62%

2 标准治疗的发展方向

诱导治疗后采用tarlatamab维持治疗

诱导治疗
度伐利尤单抗＋铂类/依托泊苷
（4个周期）

维持治疗
tarlatamab＋度伐利尤单抗

度伐利尤单抗 ＋ 铂类/依托泊苷

＋ 度伐利尤单抗 ＋ Tarlatamab（TCE）

用于符合条件且疾病未进展的患者

关键限制或阻碍

- 部分患者在进入维持治疗前发生进展（20%–30%的患者在诱导治疗期间进展）[1]
- 需监测TCE相关细胞因子释放综合征（CRS）/神经毒性
- 药物可及性、治疗中心实施能力及患者偏好可能影响临床应用

3 未来机会

一线起始 持续治疗

概念性治疗愿景

双药方案 Zoci ＋ 免疫治疗

三药方案 Zoci ＋ 免疫治疗 ＋ TCE

持续治疗直至疾病进展

不再区分诱导与维持治疗

潜在战略获益

- 在更早治疗阶段覆盖患者
- 避免患者在诱导治疗至维持治疗转换中流失
- 减少化疗依赖的持续治疗方案
- 推动zoci成为下一代联合治疗的基石ADC

Sources: (1) Horn, NEJM 2018 (IMpower133); Paz-Ares, Lancet 2019 (CASPIAN). Grade 3/4 AEs for IO + chemo: IMpower133 56.6%, CASPIAN 62% (all-cause)

Zoci + DLL3 TCE：两项全球研究探索一线三联方案用于小细胞肺癌和神经内分泌癌

- 安进和勃林格殷格翰将分别负责申办并主导各自的全球Ib/II期研究；再鼎医药将提供研究药物
- 再鼎医药将继续探索其他联合治疗方案

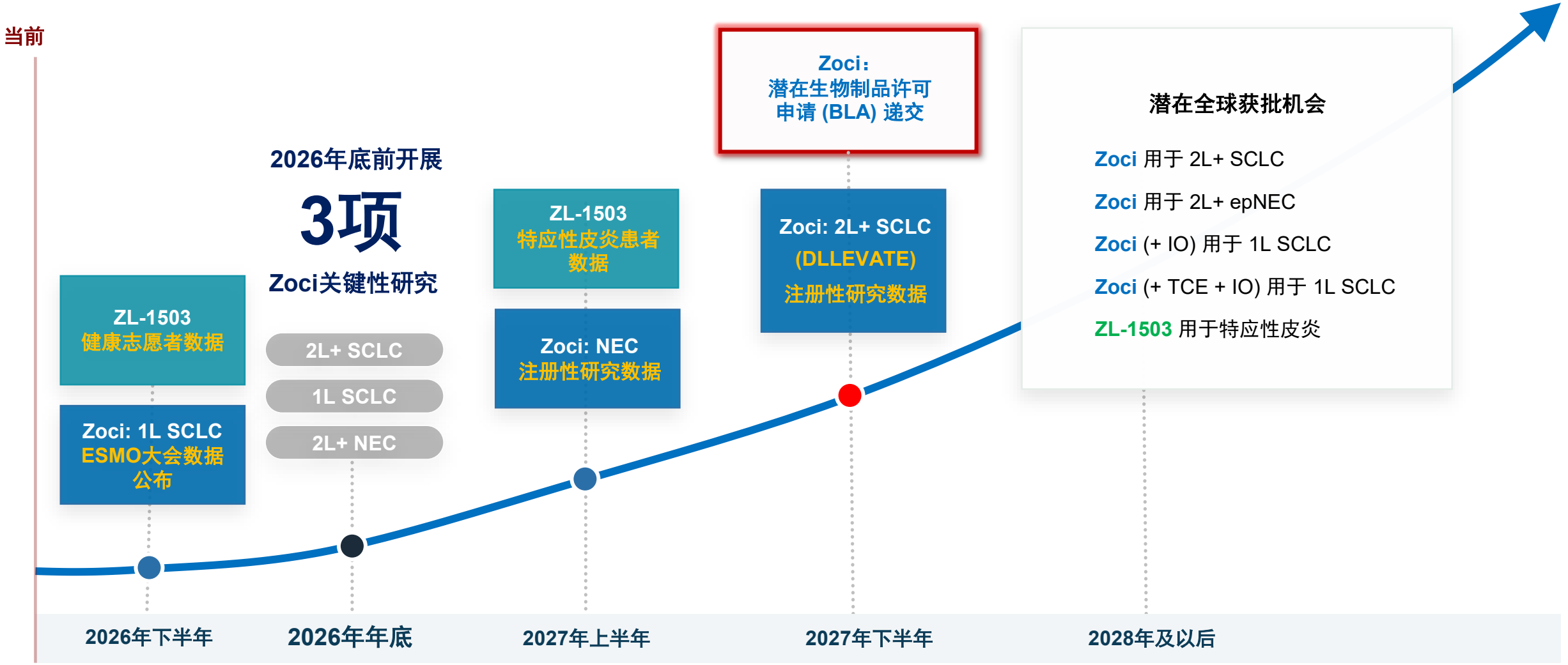
推进zoci在多个适应证和治疗阶段的开发

适应证	治疗线次	治疗方案	研究阶段	开发状态
广泛期小细胞肺癌（ES-SCLC）	2L+	Zoci 单药	III 期	III期研究正在进行中
	1L	Zoci + PD-L1	I 期	I期研究正在进行中；III期研究计划中
	1L+	Zoci + TCE ± PD-L1	Ib 期	Ib期研究正在进行中
肺外神经内分泌癌（epNEC）	2L+	Zoci 单药	I/II 期	注册性队列已完成全部患者入组
	1L+	Zoci + TCE ± PD-L1	I 期	I期研究启动中

其他计划探索的适应证：局限期小细胞肺癌（LS-SCLC）、脑瘤、肺大细胞神经内分泌癌（LCNEC）

Zoci与ZL-1503：更多拓展机遇

数据读出与监管注册申报稳步推进，未来拓展机遇持续显现



Note: SCLC = small cell lung cancer; epNEC = extrapulmonary neuroendocrine carcinomas

Q&A

APPENDIX

Abbreviations

BLA	Biologics License Application
CAF	Cancer-associated fibroblast
CR	Complete response
DAR	Drug-to-antibody ratio
DLL3	Delta-like ligand 3
DoR	Duration of response
EP	Etoposide and platinum
epNEC	Extrapulmonary neuroendocrine carcinoma
ES-SCLC	Extensive-stage small cell lung cancer
GC	Gastric cancer
GEJ	Gastroesophageal junction
Ig	Immunoglobulin
IgAN	Immunoglobulin A nephropathy
ILD	Interstitial lung disease
IO	Immuno-oncology
LCNEC	Large cell neuroendocrine carcinoma
LRRC15	Leucine-rich repeat-containing protein 15
LS-SCLC	Limited-stage small cell lung cancer
mAb	Monoclonal antibody
MAD	Multiple ascending dose
MOA	Mechanism of action
NEC	Neuroendocrine carcinoma
OMG	Ocular myasthenia gravis
ORR	Objective response rate
pMN	Primary membranous nephropathy
PS	Performance status
Q3W	Once every 3 weeks
SAD	Single ascending dose
SCLC	Small cell lung cancer
TME	Tumor microenvironment
TRAE	Treatment-related adverse event