# T-5

## Trial in progress: A Phase Ib/II, Open-label, Multi-center Study of ZL-1310 in Participants with DLL3 positive Neuroendocrine Carcinomas (NECs) and other Selected Solid Tumors

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### BACKGROUND

Neuroendocrine carcinomas (NECs) are highly aggressive cancers characterized by poor prognosis and rapid disease progression. Platinum-based chemotherapy, using either cisplatin or carboplatin plus etoposide, is recommended as the first-line therapy for advanced and metastatic disease. No standard regimen after first-line therapy has been established, underscoring the need for additional treatment options. ZL-1310 is an antibody-drug conjugate (ADC) against delta-like ligand 3 (DLL3), an inhibitory Notch pathway ligand, that is highly expressed in neuroendocrine carcinomas (NECs), including small cell lung cancer (SCLC). Recent clinical data from an ongoing Phase 1 study evaluating ZL-1310 in participants with relapsed SCLC shows encouraging results indicated that ZL-1310 is a promising agent for SCLC, and it is valuable to explore its preliminary efficacy and safety in NEC and other solid tumors with DLL3 expression. Based on these promising results, this Phase Ib/II study will evaluate safety, tolerability and the anti-tumor efficacy of ZL-1310 as a single agent in patients with locally advanced or metastatic NEC, and other solid tumors with DLL3 expression.

### METHODS

This is an ongoing Phase Ib/II study, currently enrolling in the US and China, to investigate the safety and anti-tumor effect of ZL-1310 in NECs and DLL3-expressing solid tumors. This Phase Ib study enrolls participants in two cohorts. Cohort 1 enrolls participants with previously treated Gastroenteropancreatic (GEP)-NEC, and Cohort 2 enrolls participants with de novo or treatment-emergent neuroendocrine prostate cancer (NEPC), large cell neuroendocrine cancer (LCNEC), SCLC transformed from epidermal growth factor receptor (EGFR)-mutant non-small cell lung cancer (NSCLC), other NECs or DLL3-expressing solid tumors. The primary objective in Phase Ib is to evaluate safety and tolerability of ZL-1310 as a single agent, and secondary objective is to evaluate objective response rate (ORR) and disease control rate (DCR) as measured by RECIST v1.1. Other end points are to evaluate progression-free survival (PFS), overall survival (OS), duration of response, pharmacokinetics (PK) and immunogenicity detected by incidence of anti-drug antibodies (ADAs) to

ZL-1310. Tumor response will be assessed every 6 weeks relative to the first dose of ZL-1310 for the first 30 weeks and every 9 weeks thereafter until disease progression by RECIST v1.1.

## RESULTS

N/A

## CONCLUSIONS

N/A

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