A Phase I, open-label, dose-escalation trial of BI 764532, a DLL3/CD3 bispecific antibody, in patients with small cell lung carcinoma or other neuroendocrine neoplasms expressing DLL3

Martin Wermke,*† 1 2 3 4 5 6 7 Taofeek K. Owonikoko The addition of anti-DLL3 antibodies to immunotherapy is a logical next step. DLL3 is widely expressed in small cell lung carcinoma and neuroendocrine carcinomas.

In preclinical studies, BI 764532 induced cytotoxicity of DLL3-positive tumor cells. To determine the clinical activity and safety profile of BI 764532 in patients with small cell lung carcinoma or other neuroendocrine neoplasms expressing DLL3:

Objectives
- To determine the clinical activity and safety profile of BI 764532 in patients with small cell lung carcinoma or other neuroendocrine neoplasms expressing DLL3.

Study design
- First-in-human, open-label, dose-escalation trial (NCT04429087) of BI 764532 administered IV in patients with SCLC or NEC DLL3-positive tumors (confirmed according to central review).
- DLL3 status to be assessed with the Ventana DLL3 (SP347) assay at the Roche CDx CAP/CLIA laboratory.