**What is BI 764532?**

BI 764532 is an investigational drug that brings activated T cells and DLL3 on tumor cells into the same place to release cytokines, and neuroendocrine carcinoma.

**How does it work?**

BI 764532 is a novel T cell engager (TCeng) that binds the DLL3 cell lung cancer and neuroendocrine carcinoma.

**What are the aims of the study (NCT04429087)?**

Determine MTD of BI 764532 based on DLTs for patients with DLL3-positive small-cell lung cancer.

Evaluate the safety, tolerability, and preliminary efficacy of BI 764532.

**What is the study design?**

Phase I trial in human dose-escalation trial.

**Primary endpoints**

Number of patients with DLTs in the MTD evaluation period.

**Secondary endpoints**

Objective response based on RECIST 1.1, Response Evaluation Criteria in Solid Tumors version 1.1; SCLC, small cell lung cancer; LCNEC, large cell neuroendocrine carcinoma; DLT, dose-limiting toxicity; BI 764532, a delta ligand-activated T cell engager that links DLL3 on tumor cells and neuroendocrine carcinoma.

**Regimen A**

- Dose escalation trial of BI 764532 using a 3+3 design.
- Dose: 57%, 30%, 20%, 10%, 5%.
- Route: IV dose q3w.
- Duration: 28 days.
- Dose levels: 90, 70, 50, 30, 20, 10, 5 µg/kg.

**Regimen B**

- Dose escalation trial of BI 764532 using a 3+3 design.
- Dose: 57%, 30%, 20%, 10%, 5%.
- Route: IV dose q3w.
- Duration: 28 days.
- Dose levels: 90, 70, 50, 30, 20, 10, 5 µg/kg.

**Safety (N=107)**

MTD has not been reached; dose escalation is ongoing.

**Efficacy**

Response rates for BI 764532 in a dose-ranging study.