**BACKGROUND**

- Seizure-related 6 homolog (SEZ6) is overexpressed in many tumor types with high unmet need, including small cell lung cancer (SCLC), high-grade neuroendocrine carcinomas (NECs)/neuroendocrine tumors (NETs), and central nervous system (CNS) tumors.  
- Encouraging preliminary efficacy of ABBV-011, a SEZ6 targeted antibody drug conjugate (ADC) with calicheamicin payload, established SEZ6 as a valid therapeutic target in SCLC.  
- ABBV-706 is the next generation ADC comprised of an anti-SEZ6 antibody conjugated to a topoisoerase I (Top1) inhibitor payload via a stable bromoacetamide attachment and cleavable valine-alanine linker.  
  - This linker-drug technology is identical to that used in ABBV-400, a c-Met targeted ADC currently in Phase 1 clinical development (NCT05029882).  
- Combination of ABBV-706 with platinum chemotherapy agents or a PD-1 inhibitor (budigalimab) will provide combination safety and efficacy data to help inform integration of ABBV-706 with standard-of-care (SoC) agents.

**STUDY SCHEMA**

- Open-label, phase 1, first-in-human, study in patients (≥18 years) with advanced solid tumors  
  - Part 1: ABBV-706 monotherapy dose escalation in relapsed or refractory (R/R) solid tumors, following a Bayesian optimal interval design  
  - Part 2: ABBV-706 randomized monotherapy dose optimization to inform RP2D, and expansion in R/R SCLC  
  - Part 3: Dose escalation and expansion of ABBV-706 in combination with budigalimab or platinum therapy in SCLC + NECs/NETs  
  - Part 4: Monotherapy dose expansion in R/R high-grade CNS tumors or NECs/NETs

**TRIAL DESIGN**

**Phase 1 (NCT05599894)**

- Multicenter, open-label
- Dose-escalation and expansion

**KEY PATIENT ELIGIBILITY CRITERIA**

- Key inclusion criteria  
  - Age ≥18 years  
  - ECOC score ≤1  
  - Measurable disease per Response Evaluation Criteria in Solid Tumors v1.1 or Response Assessment for Neuro-Oncology  
  - Tumor tissue available for submission for retrospective SEZ6 expression analysis  
  - One of the following histologically or cytologically confirmed advanced R/R solid tumors:  
    - Part 1: Solid tumors with potential SEZ6 expression including SCLC, high-grade CNS tumors, high-grade NECs/NETs (including neuroendocrine prostate cancer)  
    - Part 2: SCLC  
    - Part 3a: SCLC or high-grade NECs/NETs  
    - Part 3b: SCLC with progression following at least 1 complete cycle of platinum-based chemotherapy or high-grade NECs/NETs  
    - Part 4a: High-grade CNS tumors  
    - Part 4b: High-grade NECs/NETs  

- Key exclusion criteria  
  - Prior treatment with an ADC that consists of a Top1 inhibitor payload  
  - Part 2 only: Prior treatment with a SEZ6-targeted ADC

**TREATMENT**

- Monotherapy  
  - ABBV-706 will be administered intravenously until disease progression or unacceptable toxicity  
- Combination therapy  
  - Part 3a: ABBV-706 will be administered intravenously, followed by fixed dose budigalimab intravenously  
  - Part 3b: ABBV-706 will be administered intravenously, followed by carboplatin or cisplatin according to institutional guidelines

**SSTudy endpoints**

- Safety endpoints  
  - Dose-limiting toxicities  
  - Adverse events  
  - PK endpoints  
  - Cmax, tmax, t1/2, and AUC  
- Clinical benefits  
  - Objective response rate  
  - Duration of response  
  - Exploratory efficacy endpoints  
  - Clinical benefit rate  
  - Progression-free survival  
  - Overall survival  
  - Predictive biomarkers

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