

IDEate-Lung02: a Phase 3, randomized, open-label study of ifinatamab deruxtecan (I-DXd) vs treatment of Physician’s choice in relapsed small cell lung cancer

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PURPOSE

- IDEate-Lung02 (NCT06203210) is a Phase 3 trial of I-DXd in adult patients with relapsed SCLC and only 1 prior line of platinum-based therapy¹
- The study will compare I-DXd with TPC chemotherapy (topotecan, amrubicin, or lurbinectedin) to evaluate the efficacy and safety profile of I-DXd

INTRODUCTION

- Patients with ES-SCLC have few effective treatment options beyond 1L therapy, and there is a substantial unmet need for therapies that provide durable clinical benefit
 - Despite high initial response rates to combination platinum-based chemotherapy plus immunotherapy in 1L ES-SCLC, median OS is 12.3–13.0 months^{2,3}
 - Patients with brain metastases have worse survival outcomes (median OS of 8.5 months)² and remain difficult to treat⁴
 - Treatment options beyond 1L have limited efficacy (median OS of 6.0–8.1 months with topotecan, 7.5 months with amrubicin, and 9.3 months with lurbinectedin in 2L) and are associated with high rates of hematologic toxicity,^{5–8} highlighting the need for novel therapies
- B7-H3 (CD276), a type 1 transmembrane protein belonging to the B7 family, is expressed in many solid tumors but has low or no expression in normal tissue^{9–11}
- B7-H3 exhibits moderate-to-high expression in 65% of patients with SCLC, which is associated with a shorter OS (7.4 months vs 23.8 months in patients with low or absent B7-H3)¹²
- I-DXd is a B7-H3–directed ADC comprising a B7-H3 mAb linked to a topoisomerase I inhibitor payload (DXd) via a stable cleavable linker, designed to enhance selective tumor-cell death and reduce systemic exposure¹³ (**Figure 1**)
- In the Phase 1/2 IDEate-Pantumor01 study (NCT04145622), I-DXd demonstrated durable efficacy (ORR, 52.4%; median DOR, 5.9 months; median OS, 12.2 months) irrespective of B7-H3 status in 21 patients with pretreated SCLC¹⁴
- I-DXd is being investigated in a dose-optimization Phase 2 study in patients with pretreated ES-SCLC (IDEate-Lung01 [NCT05280470])¹⁵
- Here, we describe IDEate-Lung02 (NCT06203210), a Phase 3 trial comparing I-DXd with TPC (topotecan, amrubicin, or lurbinectedin) in patients with relapsed SCLC who have received only 1 prior line of platinum-based therapy¹

Figure 1. I-DXd was designed with 7 key attributes

