



# The FDA approves Amgen's Imdelltra, a landscape-changing, first-in-class DLL-3-targeted BiTE therapy

Market Event Summary

Vandana | May 2024

# Imdelltra becomes the first targeted therapy to be approved for previously treated ES-SCLC, transforming the treatment armamentarium.

## Background

- **Imdelltra is a DLL-3 / CD3 targeted BiTE** therapy. It acts by binding both CD3 expressed on T cells and DLL3 expressed on SCLC cells, leading to T-cell-mediated tumor lysis.
- The relapsed / refractory SCLC setting is **dominated by chemotherapies** with a median OS of only around 5 months, and a huge unmet need exists.
- In **December 2023**, the FDA accepted a BLA seeking approval of Imdelltra, based on the results of Phase 2 **DeLLphi-301** trial, which evaluated Imdelltra in R/R SCLC patients who have failed two or more prior lines of treatment.
- Imdelltra demonstrated an encouraging **ORR and median DOR of 40% and 9.7 months, respectively**. The median PFS and median OS were 4.9 and 14.3 months, respectively, at the median follow-up of 10.6 months. Any grade CRS was the most common TEAE, occurring in 55% of patients.

## Event

- **The FDA granted accelerated approval to Imdelltra in May 2024**, based on the results of DeLLphi-301 trial for the treatment of extensive-stage SCLC patients with disease progression on or after platinum-based chemotherapy.
- **Amgen** is also conducting the randomized, **confirmatory, Phase 3 DeLLphi-304 trial**, which is comparing **Imdelltra versus second-line SOC (Zepzelca, topotecan, amrubicin)** in second-line SCLC patients who have relapsed after platinum-based first-line chemotherapy.

## Strategic implications

### Commercial

We expect premium-priced Imdelltra to establish itself as an SOC for previously treated ES-SCLC patients, with major-market sales potential of more than \$1 billion by 2032.



### Treatment dynamics

Zepzelca is the current SOC in R/R ES-SCLC. It is a targeted chemotherapy and is available only in the United States. Hence, Imdelltra, being the first approved BiTE therapy, is anticipated to have rapid uptake, establishing itself as an SOC in SCLC patients with disease progression on or after platinum-based chemotherapy.



### Adoption in real-world setting

Premium pricing, with average cost per patient of more than \$150,500, might hinder the uptake of Imdelltra. Additionally, Imdelltra's boxed warning for CRS and ICANS could deter physicians from prescribing it owing to the increased complexity of managing these toxicities.

# About the author



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Vandana is a healthcare and research data analyst on the Oncology team at Clarivate. Previously, she worked as an analyst with WNS and has experience conducting competitive intelligence, forecasting, and pipeline analysis. She obtained her master's degree in pharmacology from the University of Delhi.

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### Clarivate coverage of small-cell lung cancer

- [Small-Cell Lung Cancer | Disease Landscape and Forecast \(G7\)](#)
- [Small-Cell Lung Cancer | Current Treatment: Physician Insights \(US\)](#) explores the current prescribing trends of medical oncologists treating SCLC.
- [Small-Cell Lung Cancer | Unmet Need:](#) provides a detailed, expanded analysis of the unmet needs in the treatment of extensive-stage SCLC
- [Small-Cell Lung Cancer | Treatment Sequencing \(US\)](#) presents surveyed medical oncologists' most frequent treatment sequences for SCLC



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