Imdelltra™ (tarlatamab-dlle) – New drug approval

- On May 16, 2024, Amgen announced the FDA approval of Imdelltra (tarlatamab-dlle), for the treatment of adult patients with extensive stage small cell lung cancer (ES-SCLC) with disease progression on or after platinum-based chemotherapy.
    - This indication is approved under accelerated approval based on overall response rate (ORR) and duration of response (DOR). Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).
- SCLC is an aggressive solid tumor malignancy. Despite initial high response rates to first-line platinum-based chemotherapy, most patients quickly relapse within months and require subsequent treatment options.
    - SCLC comprises ~15% of the 2.4 million plus patients diagnosed with lung cancer worldwide each year.
- Imdelltra is a first-in-class immunotherapy that binds to both DLL3 on tumor cells and CD3 on T cells, activating T cells to kill DLL3-expressing SCLC cells. DLL3 is a protein that is expressed on the surface of SCLC cells in approximately 85% to 96% of patients with SCLC but is minimally expressed on healthy cells.
- The efficacy of Imdelltra was established in Study DeLLphi-301, an open-label, multi-cohort study in 99 relapsed/refractory SCLC with disease progression after receiving previous treatment with platinum-based chemotherapy and at least one other line of prior therapy. The major outcome measures were ORR and DOR.
    - The ORR was 40% (95% CI: 31, 51).
    - The median DOR was 9.7 months (range: 2.7, 20.7+).
- Imdelltra carries a boxed warning for cytokine release syndrome (CRS) and neurologic toxicity including immune effector cell-associated neurotoxicity syndrome.
- Additional warnings and precautions for Imdelltra include cytopenias, infections, hepatotoxicity, hypersensitivity, and embryo-fetal toxicity.
- The most common adverse reactions (≥ 20%) with Imdelltra use were CRS, fatigue, pyrexia, dysgeusia, decreased appetite, musculoskeletal pain, constipation, anemia, and nausea. The most common grade 3 or 4 laboratory abnormalities (≥ 2%) were decreased lymphocytes, decreased sodium, increased uric acid, decreased total neutrophils, decreased hemoglobin, increased activated partial thromboplastin time, decreased potassium, increased aspartate aminotransferase, decreased white blood cells, decreased platelets, and increased alanine aminotransferase.
- The recommended intravenous dose of Imdelltra is after the step-up dosing schedule is 10 mg biweekly until disease progression or unacceptable toxicity.
    - Refer to the drug label for complete dosing and administration recommendations.

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- Amgen’s launch plans for Imdelltra are pending. Imdelltra will be available as a 1 mg and 10 mg lyophilized powder in a single-dose vial.