Emrelis™ (telisotuzumab vedotin-tllv) – New drug approval

- On May 14, 2025, AbbVie announced the FDA approval of Emrelis (telisotuzumab vedotin-tllv), for the **treatment of adult patients with locally advanced or metastatic, non-squamous non-small cell lung cancer (NSCLC) with high c-Met protein overexpression (≥ 50% of tumor cells with strong [3+] staining), as determined by an FDA-approved test, who have received a prior systemic therapy**.
    - 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).
- Approximately 85% of lung cancers are classified as NSCLC. The c-Met protein is found to be overexpressed in approximately 25% of advanced EGFR wild type, non-squamous NSCLC patients and is associated with poor prognosis. Approximately half of these cases have high c-Met overexpression, defined as ≥ 50% of tumor cells with strong (3+) staining.
- Emrelis is a first-in-class c-Met-directed antibody and microtubule inhibitor conjugate.
- The efficacy of Emrelis was established in LUMINOSITY, an open-label, single-arm, multi-cohort study in patients with locally advanced or metastatic NSCLC with c-Met protein overexpression and treatment with prior systemic therapy (including no more than one line of prior chemotherapy) in the locally advanced or metastatic setting. The major outcome measure was ORR. An additional outcome measure was DOR. The efficacy population included 84 patients with non-squamous, EGFR wild-type NSCLC with high c-Met protein overexpression who had received prior systemic therapy.
    - **The ORR was 35%** (95% CI: 24, 46).
    - The median DOR was 7.2 months (95% CI: 4.2, 12).
- Warnings and precautions for Emrelis include peripheral neuropathy, interstitial lung disease/pneumonitis, ocular surface disorders, infusion-related reactions, and embryo-fetal toxicity.
- The most common adverse reactions (≥ 20%) with Emrelis use were peripheral neuropathy, fatigue, decreased appetite, and peripheral edema. The most common Grade 3 or 4 laboratory abnormalities (≥ 2%) were decreased lymphocytes, increased glucose, increased alanine aminotransferase, increased gamma glutamyl transferase, decreased phosphorus, decreased sodium, decreased hemoglobin and decreased calcium.
- The recommended dosage of Emrelis is 1.9 mg/kg (up to a maximum of 190 mg for patients greater than or equal to 100 kg) administered as an intravenous infusion over 30 minutes every 2 weeks until disease progression or unacceptable toxicity.
    - Patients should be selected for treatment with Emrelis based on the presence of high c-Met protein overexpression (≥ 50% of tumor cells with strong [3+] staining) in patients with non-squamous NSCLC. Information on FDA-approved tests for the detection of high c-Met protein overexpression is available at: http://www.fda.gov/CompanionDiagnostics.
- AbbVie launch plans for Emrelis are pending. Emrelis will be available as a 20 mg or 100 mg lyophilized powder in a single-dose vial.