Tecvayli™ (teclistamab-cqyv) – New drug approval

- On October 25, 2022, Janssen announced the FDA approval of Tecvayli (teclistamab-cqyv), for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent and an anti-CD38 monoclonal antibody.
    - This indication is approved under accelerated approval based on response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).
- Multiple myeloma is an incurable blood cancer that affects plasma cells, which are found in the bone marrow. In multiple myeloma, these plasma cells change, spread rapidly and replace normal cells in the bone marrow with tumors.
    - In 2022, it is estimated that more than 34,000 people will be diagnosed with multiple myeloma, and more than 12,000 people will die from the disease in the U.S.
- Tecvayli is a first-in-class bispecific T-cell engaging antibody that binds to the CD3 receptor expressed on the surface of T-cells and B-cell maturation antigen (BCMA) expressed on the surface of multiple myeloma cells and some healthy B-lineage cells.
- The efficacy of Tecvayli was established in a single-arm, open-label study in 110 patients with relapsed or refractory multiple myeloma. The median number of prior lines of therapy was 5; 78% of patients had received at least 4 prior lines of therapy. Efficacy was established based on overall response rate (ORR).
    - The ORR was 61.8% (95% CI: 52.1, 70.9).
    - With a median follow-up of 7.4 months among responders, the estimated duration of response (DOR) rate was 90.6% (95% CI: 80.3, 95.7) at 6 months and 66.5% (95% CI: 38.8, 83.9) at 9 months.
- Tecvayli carries a boxed warning for cytokine release syndrome (CRS) and neurologic toxicity including immune effector cell-associated neurotoxicity syndrome (ICANS).
    - Tecvayli is available only through a restricted program called the Tecvayli Risk Evaluation and Mitigation Strategy (REMS).
- Additional warnings and precautions for Tecvayli include hepatotoxicity, infections, neutropenia, hypersensitivity and other administration reactions, and embryo-fetal toxicity.
- The most common adverse reactions (≥ 20%) with Tecvayli use were pyrexia, CRS, musculoskeletal pain, injection site reaction, fatigue, upper respiratory tract infection, nausea, headache, pneumonia, and diarrhea.
- The most common Grade 3 to 4 laboratory abnormalities (≥ 20%) with Tecvayli use were decreased lymphocytes, decreased neutrophils, decreased white blood cells, decreased hemoglobin, and decreased platelets.

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- The recommended subcutaneous dosage of Tecvayli is step-up doses of 0.06 mg/kg and 0.3 mg/kg followed by 1.5 mg/kg once weekly until disease progression or unacceptable toxicity. Refer to the drug label for the complete dosing schedule recommendations.
    - Tecvayli should be administered by a healthcare provider with adequate medical personnel and appropriate medical equipment to manage severe reactions, including CRS and ICANS.
- Janssen's launch plans for Tecvayli are pending. Tecvayli will be available as 30 mg/3 mL and 153 mg/1.7 mL single-dose vials.

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