Tecartus™ (brexucabtagene autoleucel) – New orphan drug approval

- On July 24, 2020, Gilead announced the FDA approval of Tecartus (brexucabtagene autoleucel), for the treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL) .
    - This indication is approved under accelerated approval based on overall response rate and durability of response.
    - Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

- Tecartus, a chimeric antigen receptor (CAR) T cell therapy, is the first cell-based gene therapy approved by the FDA for the treatment of MCL.

- MCL is a rare form of cancerous B-cell non-Hodgkin's lymphoma that usually occurs in middle-aged or older adults. In patients with MCL, B-cells, a type of white blood cell which help the body fight infection, change into cancer cells that start to form tumors in the lymph nodes and quickly spread to other areas of the body.

- Each dose of Tecartus is a customized treatment created using a patient's own immune system to help fight the lymphoma. The patient's T cells, a type of white blood cell, are collected and genetically modified to include a new gene that facilitates the targeting and killing of the lymphoma cells. These modified T cells are then infused back into the patient.

- The safety and efficacy of Tecartus was established in a single-arm, open-label trial of 60 adults with refractory or relapsed MCL who had previously received anthracycline- or bendamustine-containing chemotherapy, an anti-CD20 antibody, and a Bruton tyrosine kinase inhibitor [ie, Imbruvica® (ibrutinib) or Calquence® (acalabrutinib)]. The primary endpoint was objective response rate (ORR).
    - The complete remission rate after treatment with Tecartus was 62%, with an objective response rate of 87%.
    - The median time to response was 28 days (range: 24 to 92 days) with a median follow-up time for duration of response of 8.6 months.

- Tecartus carries a boxed warning for cytokine release syndrome (CRS) and neurologic toxicities.

- Other warnings and precautions of Tecartus include hypersensitivity reactions, severe infections, prolonged cytopenias, hypogammaglobulinemia, secondary malignancies, and effects on ability to drive and use machines.

- Tecartus is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the YESCARTA and TECARTUS REMS Program.
    - The risk mitigation measures for Tecartus are identical to those of the current REMS Program for another CAR-T therapy, Yescarta® (axicabtagene ciloleucel).

- The most common non-laboratory adverse reactions (≥ 20%) with Tecartus use were pyrexia, CRS, hypotension, encephalopathy, fatigue, tachycardia, arrhythmia, infection – pathogen unspecified, chills, hypoxia, cough, tremor, musculoskeletal pain, headache, nausea, edema, motor dysfunction, constipation, diarrhea, decreased appetite, dyspnea, rash, insomnia, pleural effusion, and aphasia.

- Refer to the Tecartus prescribing information for dosing recommendations.

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- Tecartus will have a list price of $373,000.
- In support of Tecartus, health care providers can utilize KiteKonnect™, a program that provides information, assistance, and resources.
- Gilead's launch plans for Tecartus are pending. Tecartus will be available as a frozen suspension of genetically modified autologous T-cells in one infusion bag labeled for the specific recipient.

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