OPTUMRx®

Abecma™ (idecabtagene vicleucel) – New orphan drug approval

- On March 27, 2021, the FDA announced the approval of Bristol Myers Squibb and bluebird bio's Abecma (idecabtagene vicleucel), for the treatment of adult patients with relapsed or refractory multiple myeloma after four or more prior lines of therapy, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody.

- Multiple myeloma is a type of blood cancer in which abnormal plasma cells build up in the bone marrow and form tumors in many bones of the body. Myeloma can also damage the bones and the kidneys and weaken the immune system.

    — According to the National Cancer Institute, myeloma accounted for approximately 1.8% (32,000) of all new cancer cases in the U.S. in 2020.

- Abecma is a B-cell maturation antigen (BCMA)-directed genetically modified autologous chimeric antigen receptor (CAR) T-cell therapy. Each dose of Abecma is a customized treatment created by using a patient's own T-cells. The patient's T-cells are collected and genetically modified to include a new gene that facilitates targeting and killing myeloma cells. Once the cells are modified, they are infused back into the patient.

    — Abecma is the first CAR T cell therapy approved for multiple myeloma.

- The efficacy of Abecma was established in KarMMa, an open-label, single-arm study in adult patients with relapsed and refractory multiple myeloma. Lymphodepleting chemotherapy was administered starting 5 days prior to the target infusion date of Abecma. A total of 100 patients were included in the efficacy evaluable population. Efficacy was established on the basis of overall response rate (ORR), complete response (CR) rate, and duration of response (DOR).

    — The ORR was 72% (95% CI: 62, 81). The CR rate was 28% (95% CI: 19, 38).
    — The median DOR was 11.0 months (95% CI: 10.3, 11.4).

- Abecma carries a boxed warning for cytokine release syndrome (CRS), neurological toxicities, hemophagocytic lymphohistiocytosis/macrophage activation syndrome (HLH/MAS), and prolonged cytopenia.

- Abecma is only available through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the Abecma REMS.

    — The FDA is requiring, among other things, that hospitals and their associated clinics that dispense Abecma be specially certified and staff involved in the prescribing, dispensing or administering of Abecma are trained to recognize and manage CRS and nervous system toxicities and other side effects of Abecma. Also, patients must be informed of the potential serious side effects and of the importance of promptly returning to the treatment site if side effects develop after receiving Abecma.

- Additional warnings and precautions for Abecma include hypersensitivity reactions, infections, hypogammaglobulinemia, secondary malignancies, and effects on ability to drive and use machines.

- The most common nonlaboratory adverse reactions (≥ 20%) with Abecma use were CRS, infections (pathogen unspecified), fatigue, musculoskeletal pain, hypogammaglobulinemia, diarrhea, upper respiratory tract infection, nausea, viral infections, encephalopathy, edema, pyrexia, cough, headache, and decreased appetite.

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- The most common laboratory adverse reactions (≥ 50%) with Abecma use were neutropenia, leukopenia, lymphopenia, thrombocytopenia, and anemia.
- Refer to the Abecma drug label for dosing and administration recommendations.
- Abecma will be priced at $419,500 for the one-time dose.
- Bristol Myers Squibb's and bluebird bio's launch plans for Abecma are pending.

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