Abecma® (idecabtagene vicleucel) – Expanded indication

- On April 5, 2024, Bristol Myers Squibb and 2seventy bio announced the FDA approval of Abecma (idecabtagene vicleucel), for the treatment of adult patients with relapsed or refractory multiple myeloma after two or more prior lines of therapy including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody.
    - Abecma was previously approved for this indication after four or more prior lines of therapy, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody.
- The approval of Abecma for the expanded indication was based on KarMMa-3, an open-label, randomized, controlled study in 386 adult patients with relapsed and refractory multiple myeloma who had received two to four prior antimyeloma. Patients were randomized to receive either Abecma or standard regimens. The primary endpoint was progression free survival (PFS). Other efficacy measures included overall response rate (ORR) and overall survival (OS).
    - Median PFS was 13.3 months with Abecma vs. 4.4 months with standard regimens (hazard ratio 0.49, 95% CI: 0.38, 0.64; $p < 0.0001$).
    - The ORR was 71% (95% CI: 66, 77) with Abecma vs. 42% (95% CI: 33, 50) with standard regimens ($p < 0.0001$).
    - The OS curves cross at month 15 of the study rendering the overall hazard ratio unreliable to estimate the treatment effect on OS.
- Abecma carries a boxed warning for cytokine release syndrome; neurologic toxicities; hemophagocytic lymphohistiocytosis/macrophage activation syndrome; prolonged cytopenia; and secondary hematological malignancies.
- Abecma is provided as a single dose for infusion containing a suspension of chimeric antigen receptor (CAR)-positive T cells in one or more infusion bags. The recommended dose range is 300 to 510 x 10^6 CAR-positive T cells.