Carvykti® (ciltacabtagene autoleucel) – Expanded indication

- On April 5, 2024, Johnson & Johnson announced the FDA approval of Carvykti (ciltacabtagene autoleucel), for the treatment of adult patients with relapsed or refractory multiple myeloma, who have received at least one prior line of therapy, including a proteasome inhibitor and an immunomodulatory agent, and are refractory to lenalidomide.
    - Carvykti was previously approved for this indication after four or more prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody.
- The approval of Carvykti for the expanded indication was based on CARTITUDE-4, a randomized, open label, controlled study in 419 adult patients with relapsed and lenalidomide-refractory multiple myeloma. Patients were randomized to receive either Carvykti or standard therapy. The primary endpoint was progression free survival (PFS).
    - Median PFS was not estimable in the Carvykti arm vs. 12 months in the standard therapy arm (hazard ratio 0.41, 95% CI: 0.30, 0.56; $p < 0.0001$).
    - The ORR was 84.6% (95% CI: 79.0, 89.2) in the Carvykti arm vs. 67.8% (95% CI: 61.0, 74.0) in the standard therapy arm ($p < 0.0001$).
- Carvykti carries a boxed warning for cytokine release syndrome; neurologic toxicities; hemophagocytic lymphohistiocytosis/macrophage activation syndrome; prolonged and recurrent cytopenia; and secondary hematological malignancies.

  Carvykti is provided as a single dose for infusion containing a suspension of chimeric antigen receptor (CAR)-positive viable T cells in one infusion bag. The recommended dose range is 0.5-1.0×10^6 CAR-positive viable T cells per kg of body weight, with a maximum dose of 1×10^8 CAR-positive viable T cells per single infusion.