Carvykti® (ciltacabtagene autoleucel) – Boxed warning added

- On December 21, 2023, the FDA approved a label update to Janssen's Carvykti (ciltacabtagene autoleucel), adding a *Boxed Warning* for secondary hematological malignancies.
    - Previously, the label for Carvykti included a regular warning for secondary malignancies.
- Myeloid neoplasms (five cases of myelodysplastic syndrome, three cases of acute myeloid leukemia and two cases of myelodysplastic syndrome followed by acute myeloid leukemia) occurred in 10% (10/97) of patients in CARTITUDE-1 study following treatment with Carvykti. The median time to onset of myeloid neoplasms was 485 days (range: 162 to 1040 days) after treatment. Nine of these 10 patients died following the development of myeloid neoplasms; Four of the 10 cases of myeloid neoplasm occurred after initiation of subsequent antimyeloma therapy. Cases of myelodysplastic syndrome and acute myeloid leukemia have also been reported in the post marketing setting.
    - Life-long monitoring for secondary malignancies is recommended after treatment with Carvykti. If a secondary malignancy occurs, Janssen should be contacted at 1-800-526-7736 for reporting and to obtain instructions on collection of patient samples.
- Carvykti is a B-cell maturation antigen (BCMA)-directed genetically modified autologous T cell immunotherapy indicated for the treatment of adult patients with relapsed or refractory multiple myeloma, after four or more prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody.
- In addition to secondary hematological malignancies, Carvykti carries boxed warnings for cytokine release syndrome; neurologic toxicities; hemophagocytic lymphohistiocytosis/ macrophage activation syndrome; and prolonged and recurrent cytopenia.
    - Carvykti is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the Carvykti REMS Program.