## Tecartus® (brexucabtagene autoleucel) – New indication

- On October 1, 2021, Gilead announced the FDA approval of Tecartus (brexucabtagene autoleucel), for the treatment of adult patients with relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL).

- Tecartus is also approved for the treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL).

- The approval of Tecartus for the new indication was based on ZUMA-3, an open-label, single-arm study in adult patients with relapsed or refractory B-cell precursor ALL. Treatment consisted of lymphodepleting chemotherapy followed by a single intravenous infusion of Tecartus. The efficacy endpoints included overall complete remission (OCR) and complete remission (CR). The evaluable efficacy population was 54 patients.

    — In the efficacy evaluable patients, the OCR rate was 64.8%. The CR rate was 51.9%. The duration of remission was 13.6 months (95% CI: 9.4, not estimable).

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

- The most common non-laboratory adverse reactions (≥ 20%) with Tecartus use for ALL were fever, CRS, hypotension, encephalopathy, tachycardia, nausea, chills, headache, fatigue, febrile neutropenia, diarrhea, musculoskeletal pain, hypoxia, rash, edema, tremor, infection with pathogen unspecified, constipation, decreased appetite, and vomiting.

- Tecartus is a CD19-directed genetically modified autologous T cell immunotherapy. Refer to the Tecartus drug label for dosing and administration recommendations.