Blincyto® (blinatumomab) – New indication

- On June 14, 2024, Amgen announced the FDA approval of Blincyto (blinatumomab), for the treatment of CD19-positive Philadelphia chromosome-negative B-cell precursor acute lymphoblastic leukemia (ALL) in the consolidation phase of multiphase chemotherapy in adult and pediatric patients one month and older.

- Blincyto is also approved for the treatment of CD19-positive B-cell precursor ALL in first or second complete remission with minimal residual disease (MRD) greater than or equal to 0.1% in adult and pediatric patients one month and older and for the treatment of relapsed or refractory CD19-positive B-cell precursor ALL in adult and pediatric patients one month and older.

- The approval of Blincyto for the new indication was based on Study E1910, a randomized, controlled study in 224 adult patients with newly diagnosed Philadelphia chromosome-negative B-cell precursor ALL. Eligible patients in hematologic complete remission (CR) or CR with incomplete peripheral blood count recovery following induction and intensification chemotherapy were randomized to receive a consolidation regimen comprised of multiple cycles of Blincyto monotherapy in addition to multiple cycles of intensive chemotherapy (Blincyto arm) or to intensive chemotherapy alone (chemotherapy arm). Efficacy was established on the basis of overall survival (OS).

    — The 3-year OS estimate was 84.8% in the Blincyto arm vs. 69.0% in the chemotherapy arm (hazard ratio [HR] 0.42, 95% CI: 0.24, 0.75; p = 0.003).

- The efficacy of Blincyto was also evaluated in Study 20120215, a randomized, controlled, open-label study in 111 patients 28 days to 18 years old with high-risk, first-relapsed, Philadelphia chromosome-negative B-cell precursor ALL with < 25% blasts in the bone marrow after induction and 2 cycles of consolidation chemotherapy. Patients were randomized to receive Blincyto or the IntReALLHR2010 HC3 intensive combination chemotherapy as the third cycle of consolidation. Efficacy was established on the basis of OS and relapse-free survival (RFS).

    — The 5-year OS estimate was 78.4% in the Blincyto arm vs. 41.4% in the chemotherapy arm (HR 0.35, 95% CI: 0.17, 0.70).
    — The 5-year RFS estimate was 61.1% in the Blincyto arm vs. 27.6% in the chemotherapy arm (HR 0.38, 95% CI: 0.22, 0.66).

- Blincyto carries a boxed warning for cytokine release syndrome and neurological toxicities including immune effector cell-associated neurotoxicity syndrome.

- A single cycle of Blincyto monotherapy in consolidation is 28 days of continuous infusion followed by a 14-day treatment-free interval (total 42 days).

    — Refer to the Blincyto drug label for complete dosing and administration recommendations in consolidation and for its other indications.