Blincyto® (blinatumomab) – Expanded Dosing and New Warnings

- On September 1, 2016, Amgen announced the FDA approval of Blincyto (blinatumomab) to include new data supporting the treatment of pediatric patients with Philadelphia chromosome-negative relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL).
    - This indication was approved under accelerated approval, and continued approval may be contingent upon verification of clinical benefit in subsequent trials.
    - Prior to this approval, information on the use of Blincyto in pediatric patients was limited. Thus, dosing in patients < 45 kg was not provided.
- The expanded approval for Blincyto is based on results from a phase 1/2, open-label, single-arm study, which evaluated the efficacy and safety of Blincyto in pediatric patients with relapsed or refractory B-cell precursor ALL.
    - In addition, the steady-state concentrations of Blincyto were shown to be comparable in adult and pediatric patients at the equivalent dose levels based on body surface area-based regimens.
- Blincyto carries a boxed warning regarding cytokine release syndrome and neurological toxicities.
- The updated label for Blincyto also includes new warnings regarding pancreatitis and immunization.
    - Fatal pancreatitis has been reported in patients receiving Blincyto in combination with dexamethasone in clinical trials and the post-marketing setting. Patients who develop signs and symptoms of pancreatitis should be evaluated. Management of pancreatitis may require either temporary interruption or discontinuation of Blincyto and dexamethasone.
    - In addition, the safety of immunization with live viral vaccines during or following Blincyto therapy has not been studied. Vaccination with live virus vaccines is not recommended for at least 2 weeks prior to the start of Blincyto treatment, during treatment, and until immune recovery following last cycle of Blincyto.
- A single treatment cycle of Blincyto consists of 28 days of continuous intravenous infusion followed by a 14-day treatment-free interval (total 42 days). A treatment course consists of up to 2 cycles of Blincyto for induction followed by 3 additional cycles for consolidation treatment (up to a total of 5 cycles).
    - For patients weighing < 45 kg, in cycle 1, administer Blincyto at 5 mcg/m^2 per day on days 1 – 7 and at 15 mcg/m^2 per day on days 8 – 28. For subsequent cycles, administer Blincyto at 15 mcg/m^2 per day on days 1 - 28.
    - For patients weighing ≥ 45 kg, in cycle 1, administer Blincyto at 9 mcg/day on days 1 – 7 and at 28 mcg/day on days 8 – 28. For subsequent cycles, administer Blincyto at 28 mcg/day on days 1-28.
    - Hospitalization is recommended for the first 9 days of the first cycle and the first 2 days of the second cycle. For all subsequent cycle starts and re-initiation (eg, if treatment is interrupted for 4 or more hours), supervision by a healthcare professional or hospitalization is recommended.
    - Premedication with dexamethasone is recommended.