Blincyto® (blinatumomab) – Expanded indication

- On July 11, 2017, Amgen announced the FDA approval of Blincyto (blinatumomab) injection, for the treatment of relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL) in adults and children.
    - Previously, Blincyto was only approved for the treatment of Philadelphia (Ph) chromosome-negative relapsed or refractory B-cell precursor ALL.
- The approval of Blincyto's expanded indication was based on a single-arm trial, which evaluated the efficacy of Blincyto in adult patients with Ph-positive relapsed or refractory B-cell precursor ALL. The endpoint was complete remission (CR) rate, duration of CR, and proportion of patients with a minimum residual disease (MRD)-negative CR/CR with partial hematological recovery (CR/CRh*) within 2 cycles of treatment.
    - CR was achieved in 31% of patients (95% CI: 18, 47). CR/CRh* was achieved in 36% of patients (95% CI: 22, 51).
    - The duration of CR was 6.7 months (range: 3.6 – 12.0 months).
- In addition, the FDA granted approval to include overall survival (OS) data to the drug label based on the TOWER study. This approval converts Blincyto's accelerated approval to a full approval.
    - In the study, Blincyto demonstrated superior improvement in median OS vs. standard of care chemotherapy (7.7 months vs. 4 months, HR = 0.71 [95% CI: 0.55, 0.93]; p = 0.012).
- Blincyto carries a boxed warning regarding the risk of cytokine release syndrome and neurological toxicities.
- A treatment course consists of up to 2 cycles of Blincyto for induction, followed by 3 additional cycles for consolidation and up to 4 additional cycles of continued therapy.
    - A single cycle of treatment of induction or consolidation consists of 28 days of continuous intravenous (IV) infusion followed by a 14 days treatment-free interval (total of 42 days).
    - A single cycle of continued therapy consists of 28 days of continuous IV infusion followed by a 56 day treatment-free interval (total of 84 days).
    - 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, supervision by a healthcare professional or hospitalization is recommended.
    - Patients should be premedicated with dexamethasone.
    - Refer to the Blincyto drug label for specific dosing recommendations by patient weight or body surface area.