Blincyto™ (blinatumomab) – Expanded orphan indication

- On March 29, 2018, the FDA announced the approval of Amgen's Blincyto (blinatumomab) for the treatment of B-cell precursor acute lymphoblastic leukemia (ALL) in first or second complete remission with minimal residual disease (MRD) greater than or equal to 0.1% in adults and children.
    - Previously, Blincyto was approved for the treatment of relapsed or refractory B-cell precursor ALL in adults and children.
- B-cell precursor ALL is a rapidly progressing type of cancer in which the bone marrow makes too many B-cell lymphocytes, an immature type of white blood cell. MRD is the presence of malignant cells detectable with more sensitive testing methods despite complete remission by standard assessment. MRD represents a significant risk factor for relapse.
    - The National Cancer Institute estimates that approximately 5,960 people in the U.S. will be diagnosed with ALL this year and approximately 1,470 will die from the disease.
- Blincyto is the first FDA-approved treatment for patients with MRD-positive ALL.
- The efficacy of Blincyto in MRD-positive ALL was demonstrated in the open-label BLAST study treating 86 adults in first or second complete remission. Efficacy was based on achievement of undetectable MRD within one cycle of Blincyto treatment and hematological relapse-free survival (RFS).
    - Undetectable MRD was achieved by 81.4% of patients (95% CI: 71.6, 89.0).
    - The median hematological RFS was 22.3 months.
- Blincyto carries boxed warnings for cytokine release syndrome and neurological toxicities.
- The recommended dose of Blincyto for patients ≥ 45 kg is 28 mcg/day from days 1 - 28 of the cycle, followed by a 14-day treatment-free interval. Up to 3 additional consolidation cycles may be provided.
    - For patients < 45 kg, the dose is calculated using the patient's body surface area. Refer to the Blincyto drug label for dosing recommendations