Imbruvica® (ibrutinib) – Expanded indication, new formulation approval

- On August 24, 2022, J&J and AbbVie announced the FDA approval of Imbruvica (ibrutinib), for the treatment of adult and pediatric patients age 1 year and older with chronic graft-versus-host disease (cGVHD) after failure of one or more lines of systemic therapy.
    - Imbruvica was previously approved for this indication in adults only.
- Imbruvica is also approved for the treatment of adult patients with mantle cell lymphoma; chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL); CLL/SLL with 17p deletion; Waldenström's macroglobulinemia; and marginal zone lymphoma.
- The approval of Imbruvica for the expanded indication was based on iMAGINE, an open-label, single-arm study in 47 pediatric and young adult patients age 1 year to less than 22 years with moderate or severe cGVHD. The primary endpoint was overall response rate (ORR) through week 25, where overall response included complete response or partial response according to the 2014 National Institutes of Health (NIH) Consensus Development Project Response Criteria.
    - The ORR was 60% (95% CI: 44, 74).
    - The median duration of response was 5.3 months (95% CI: 2.8, 8.8).
- In addition to the expanded indication, J&J and AbbVie also announced the approval of a new oral suspension formulation of Imbruvica (70 mg/mL). Imbruvica was previously available as a capsule and tablet.
- The recommended dosage of Imbruvica for patients age 12 years and older with cGVHD is 420 mg orally once daily, and for patients 1 to less than 12 years of age with cGVHD is 240 mg/m^2 orally once daily (up to a dose of 420 mg), until cGVHD progression, recurrence of an underlying malignancy, or unacceptable toxicity.
    - When a patient no longer requires therapy for the treatment of cGVHD, Imbruvica should be discontinued considering the medical assessment of the individual patient.
    - Refer to the Imbruvica drug label for dosing for all its other indications.
- The launch plans for Imbruvica oral suspension are pending.