Imbruvica® (ibrutinib) – New formulation approval

- On February 16, 2018, the FDA approved Pharmacyclic's Imbruvica (ibrutinib) tablets, which shares the same indications as Imbruvica capsules.

- Imbruvica is approved in adult patients for the following indications:

    - Treatment of mantle cell lymphoma (MCL) who have received at least one prior therapy
    - Treatment of chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL)
    - Treatment of CLL/SLL with 17p deletion
    - Treatment of Waldenström's macroglobulinemia (WM)
    - Treatment of marginal zone lymphoma (MZL) who require systemic therapy and have received at least one prior anti-CD20-based therapy
    - Treatment of chronic graft-versus-host disease (cGVHD) after failure of one or more lines of systemic therapy

- The approval of Imbruvica tablets was based on the efficacy and safety data of Imbruvica capsules.

- Warnings and precautions of Imbruvica include hemorrhage, infections, cytopenias, cardiac arrhythmias, hypertension, second primary malignancies, tumor lysis syndrome, and embryo fetal toxicity.

- The most common adverse reactions (≥ 20%) with Imbruvica use in patients with B-cell malignancies (MCL, CLL/SLL, WM and MZL) were neutropenia, thrombocytopenia, diarrhea, anemia, musculoskeletal pain, rash, nausea, bruising, fatigue, hemorrhage, and pyrexia.

- The most common adverse reactions (≥ 20%) with Imbruvica use in patients with cGVHD were fatigue, bruising, diarrhea, thrombocytopenia, muscle spasms, stomatitis, nausea, hemorrhage, anemia, and pneumonia.

- The recommended dosage of Imbruvica varies by specific indication.

    - In MCL and MZL patients, the recommended dosage of Imbruvica is 560 mg orally once daily.
    - In CLL/SLL, WM, and cGVHD patients, the recommended dosage of Imbruvica is 420 mg orally once daily.
    - Do not open, break, or chew the capsules. Do not cut, crush, or chew the tablets.

- Janssen's launch plans for Imbruvica tablets are pending. Imbruvica will be available as 140 mg, 280 mg, 420 mg, and 560 mg tablets.