Imbruvica® (ibrutinib) – New indication

- On August 2, 2017, the FDA announced the approval of Pharmacyclics' Imbruvica (ibrutinib) for the treatment of adult patients with chronic graft versus host disease (cGVHD) after failure of one or more lines of systemic therapy.

- Imbruvica is also FDA-approved for the treatment of adult patients with mantle cell lymphoma (MCL) who have received at least one prior therapy, chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL), CLL/SLL with 17p deletion, marginal zone lymphoma (MZL) who require systemic therapy and have received at least one prior anti-CD20-based therapy, and Waldenström's macroglobulinemia (WM).

- cGVHD is a severe, potentially life-threatening consequence of stem cell or bone marrow transplant. cGVHD occurs when cells from the stem cell transplant attack healthy cells in a patient's tissues. Symptoms of cGVHD can occur in the skin, eyes, mouth, gut, liver, and lungs. The condition is estimated to occur in 30 – 70% of all patients who receive a stem cell transplant.

- Imbruvica is a Bruton's tyrosine kinase inhibitor and the first therapy approved for the treatment of cGVHD.

- Approval for the new indication was based on an efficacy and safety single-arm study of 42 patients with cGVHD whose symptoms persisted despite standard treatment with corticosteroids.

    — Overall response rate was seen in 67% (95% CI: 51, 80) of patients.
    — In 48% of patients, sustained response rate lasted for at least 20 weeks.

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

- The recommended dose of Imbruvica for cGVHD, CLL/SLL and WM is 420 mg (three 140 mg capsules) orally once daily until disease progression or unacceptable toxicity.

- The recommended dose for Imbruvica for MZL and MCL is 560 mg (four 140 mg capsules) orally once daily until disease progression or unacceptable toxicity.