Imbruvica® (ibrutinib) – New Indication

- On January 19, 2017, AbbVie announced the FDA approval of Imbruvica (ibrutinib) for the treatment of patients with marginal zone lymphoma (MZL) who require systemic therapy and have received at least one prior anti-CD20-based therapy.

- Imbruvica is also FDA-approved for the treatment of 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, and Waldenström's macroglobulinemia (WM).

- According to the Lymphoma Research Foundation, MZLs are a group of slow-growing non-Hodgkin's B-cell lymphomas, which account for approximately 12% of all B-cell lymphomas. The median age of diagnosis is 65 years old.

- Approval of the new indication was based on a safety and efficacy study of 63 patients with MZL who were treated with at least one prior anti-CD20-based therapy.

    — The overall response rate was achieved in 46% of the patients (95% CI: 33.4, 59.1).
    — The median duration of response was not reached (range 16.7 months - NR).
    — The median follow-up time was 19.4 months.

- 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.

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