Imbruvica® (ibrutinib) – Expanded indication

- On January 28, 2019, AbbVie announced the FDA approval of Imbruvica (ibrutinib) for use in combination with Gazyva® (obinutuzumab) for adult patients with previously untreated chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL).
    - The approval expands the use of Imbruvica, which can already be administered as a single agent or in combination with bendamustine (Treanda®, Bendeka™) and Rituxan® (rituximab) for adult CLL/SLL patients.
    - Imbruvica is also approved for mantle cell lymphoma, CLL/SLL with 17p deletion, Waldenström's macroglobinemia, marginal zone lymphoma, and chronic graft versus host disease.

- The expanded indication is supported by efficacy data from a clinical study of 229 patients with treatment naïve CLL or SLL. Patients were randomized to receive combination treatment with Imbruvica plus Gazyva or chlorambucil plus Gazyva. The primary efficacy endpoints were progression free survival (PFS) and overall response rate (ORR).
    - After a median follow-up time of 31 months, patients treated with Imbruvica experienced a 77% reduction in risk of disease progression or death vs. those treated with chlorambucil (HR = 0.23; 95% CI: 0.15, 0.37; $p < 0.0001$).
    - The median PFS was not evaluable in the Imbruvica arm vs. 19.0 months (95% CI: 15.1, 22.1) in the chlorambucil arm.
    - The ORR was 88.5% with Imbruvica vs. 73.3% with chlorambucil.

- The recommended dose of Imbruvica for CLL/SLL as a single agent, or in combination with bendamustine and Rituxan or with Gazyva for CLL/SLL is 420 mg orally once daily until disease progression or unacceptable toxicity.
    - When administering Imbruvica in combination with Rituxan or Gazyva, consider administering Imbruvica prior to Rituxan or Gazyva when given on the same day.
    - Consult the Gazyva drug label for dosing recommendations.
    - Consult the Imbruvica drug label for dosing information for all other indications.