Imbruvica® (ibrutinib) – Indication and strength removals

- On May 18, 2023, the FDA approved revisions to the Imbruvica (ibrutinib) label to voluntarily remove the following indications:
    - Treatment of adult patients with mantle cell lymphoma (MCL) who have received at least one prior therapy
    - Treatment of adult patients with marginal zone lymphoma (MZL) who require systemic therapy and have received at least one prior anti-CD20-based therapy.
- In addition to the indication removals, the FDA also approved the removal of the Imbruvica 560 mg tablet. This strength was specifically approved for MCL and MZL.
- The FDA previously granted approval for Imbruvica in MCL and MZL based on overall response rates in two Phase 2 clinical studies under the accelerated approval pathway.
- The FDA approved label revisions follow an April 6 announcement from Janssen and AbbVie that they would be voluntarily withdrawing the MCL and MZL indications based on the results of the confirmatory Phase 3 trials.
- This decision does not affect any other approved indications for Imbruvica. Refer to the Imbruvica drug label for a complete list of Imbruvica's other approved uses.