Imbruvica® (ibrutinib) – Indication withdrawals

- On April 6, 2023, Janssen and AbbVie announced that they intend to voluntarily withdraw the indications for Imbruvica (ibrutinib) for the treatment of adult patients with mantle cell lymphoma (MCL) who have received at least one prior therapy and adult patients with marginal zone lymphoma (MZL) who require systemic therapy and have received at least one prior anti-CD20-based therapy.
    - This decision was made in consultation with the FDA, consistent with FDA procedural guidance on accelerated approvals.
    - Janssen will be communicating directly with healthcare professionals to help support patients currently receiving treatment with Imbruvica for MCL or MZL.
- 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.
- 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. Continued approval was contingent upon demonstration of clinical benefit in the confirmatory Phase 3 SHINE study in previously untreated patients with MCL, and the confirmatory Phase 3 SELENE study in patients with relapsed or refractory (R/R) follicular lymphoma (FL) or MZL.
    - After discussing the study results, the FDA advised that the primary outcomes from the Phase 3 confirmatory studies for the indications were considered insufficient to support conversion to full approval.
- The Phase 3 SHINE study met its primary endpoint and demonstrated a significant progression-free survival advantage in patients with previously untreated MCL but did not show an overall survival advantage. The addition of Imbruvica to chemoimmunotherapy was associated with increased adverse reactions compared to the placebo-controlled arm.
- The Phase 3 SELENE study did not meet its primary endpoint of progression-free survival in patients with R/R FL or MZL.