Xpovio® (selinexor) – Expanded indication

- On December 18, 2020, Karyopharm Therapeutics announced the FDA approval of Xpovio (selinexor), in combination with bortezomib (eg, Velcade®) and dexamethasone, for the treatment of adult patients with multiple myeloma who have received at least one prior therapy.

- Xpovio is also approved:

  — In combination with dexamethasone, for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least four prior therapies and whose disease is refractory to at least two proteasome inhibitors, at least two immunomodulatory agents, and an anti-CD38 monoclonal antibody.
  — For the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL), not otherwise specified, including DLBCL arising from follicular lymphoma, after at least 2 lines of systemic therapy.

- The approval of Xpovio for the expanded indication was based on the BOSTON trial, a randomized, open-label, active-controlled study in 402 adult patients who had received 1 to 3 prior anti-multiple myeloma regimens. Patients received Xpovio in combination with bortezomib plus low-dose dexamethasone or bortezomib plus dexamethasone, until disease progression or unacceptable toxicity. The primary endpoint was progression-free survival (PFS). A key secondary endpoint was overall response rate (ORR).

  — Median PFS was 13.9 months (95% CI: 11.7, not reached) for the Xpovio combination arm vs. 9.5 months for the bortezomib plus dexamethasone arm (hazard ratio 0.70; 95% CI: 0.53, 0.93; p = 0.0075).
  — The ORR was 76.4% (95% CI: 69.8, 82.2) for the Xpovio combination arm vs. 62.3% (95% CI: 55.3, 68.9) for the bortezomib plus dexamethasone arm (p = 0.0012).

- The most common adverse reactions (≥ 20%) with Xpovio plus bortezomib and dexamethasone were fatigue, nausea, decreased appetite, diarrhea, peripheral neuropathy, upper respiratory tract infection, decreased weight, cataract and vomiting. Grade 3 to 4 laboratory abnormalities (≥ 10%) were thrombocytopenia, lymphopenia, hypophosphatemia, anemia, hyponatremia and neutropenia.

- When used in combination with bortezomib and dexamethasone, the recommended dosage of Xpovio is 100 mg taken orally once weekly on day 1 of each week until disease progression or unacceptable toxicity in combination with:

  — Bortezomib 1.3 mg/m^2 administered subcutaneously once weekly on day 1 of each week for 4 weeks followed by 1 week off.
  — Dexamethasone 20 mg taken orally twice weekly on days 1 and 2 of each week.

— Refer to the bortezomib and dexamethasone drug labels for additional dosing information.
— Refer to the Xpovio drug label for dosing for its other uses.