FDA Approves Xpovio for Refractory or Relapsed Multiple Myeloma

Xpovio (selinexor) was approved for adults with multiple myeloma who have received at least one prior therapy.

December 20, 2020 By Food and Drug Administration (FDA)

On December 18, 2020, the Food and Drug Administration approved selinexor (XPOVIO, Karyopharm Therapeutics Inc.) in combination with bortezomib and dexamethasone for the treatment of adult patients with multiple myeloma who have received at least one prior therapy.

FDA granted selinexor accelerated approval in 2019 in combination with dexamethasone for the treatment of adult patients with relapsed or refractory multiple myeloma (RRMM) who 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.

Efficacy of selinexor in combination with bortezomib and dexamethasone was evaluated in the BOSTON Trial (KCP-330-023, NCT03110562), a randomized (1:1) open-label, multicenter, active comparator-controlled trial in patients with RRMM who had previously received at least one and at most three prior therapies. Patients received once-weekly selinexor orally in combination with once-weekly bortezomib subcutaneous and low-dose dexamethasone twice-weekly orally (SVd) compared to the standard twice-weekly bortezomib plus low-dose dexamethasone (Vd).

The main efficacy outcome measure was progression free survival (PFS) assessed by an independent review committee using International Myeloma Working Group response criteria. The estimated median PFS was 13.9 months (95% CI: 11.7, Not Estimable) for the SVd arm and 9.5 months (95% CI: 7.6, 10.8) for the Vd arm (estimated hazard ratio 0.70; 95% CI: 0.53, 0.93).

Common adverse reactions reported in at least 20% of patients include nausea, fatigue, decreased appetite, diarrhea, peripheral neuropathy, upper respiratory tract infection decreased weight, cataract and vomiting. Grade 3-4 laboratory abnormalities (≥10%) are thrombocytopenia, lymphopenia, hypophosphatemia, anemia hyponatremia and neutropenia.

The prescribing information provides warnings and precautions for thrombocytopenia, neutropenia, gastrointestinal toxicity, hyponatremia, serious infection, neurological toxicity, embryo-fetal toxicity and cataract.

The recommended selinexor dose is 100 mg orally once weekly on day 1 of each week of a 35-day

cycle 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.

Instruct patients to swallow tablets whole and not to crush or chew tablets.

View full prescribing information for Xpovio.

This application was granted regular review and orphan drug designation. A description of FDA expedited programs is in the Guidance for Industry: Expedited Programs for Serious Conditions-Drugs and Biologics.

Healthcare professionals should report all serious adverse events suspected to be associated with the use of any medicine and device to FDA's MedWatch Reporting System or by calling 1-800-FDA-1088.

For assistance with single-patient INDs for investigational oncology products, healthcare professionals may contact OCE's Project Facilitate at 240-402-0004 or email OncProjectFacilitate@fda.hhs.gov.

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