FDA Approves Talvey for Relapsed or Refractory Multiple Myeloma

Talquetamab is indicated for patients who have tried at least four prior lines of treatment.

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FDA grants accelerated approval to talquetamab-tgvs for relapsed or refractory multiple myeloma

On August 9, 2023, the Food and Drug Administration granted accelerated approval to talquetamab-tgvs (Talvey, Janssen Biotech, Inc.) adults with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody.

View full prescribing information for Talvey.

Efficacy was evaluated in MMY1001 (MonumenTAL-1) (NCT03399799, NCT4634552), a single-arm, open-label, multicenter study that included 187 patients who had previously received at least four prior systemic therapies. Patients received talquetamab-tgvs 0.4 mg/kg subcutaneously weekly, following two step-up doses in the first week of therapy, or talquetamab-tgvs 0.8 mg/kg subcutaneously biweekly (every 2 weeks), following three step-up doses, until disease progression or unacceptable toxicity.

The main efficacy outcome measures were overall response rate (ORR) and duration of response (DOR) as assessed by an Independent Review Committee using IMWG criteria. The primary efficacy population consisted of patients who had previously received at least 4 prior lines of therapies, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody.

ORR in the 100 patients receiving 0.4 mg/kg weekly was 73% (95% confidence interval (CI): 63.2%, 81.4%) and median DOR was 9.5 months (95% CI: 6.5, not estimable). ORR in the 87 patients receiving 0.8 mg/kg biweekly was 73.6% (95% CI: 63%, 82.4%) and median DOR was not estimable. An estimated 85% of responders maintained response for at least 9 months.

The prescribing information for talquetamab-tgvs has a Boxed Warning for life threatening or fatal cytokine release syndrome (CRS) and neurologic toxicity, including immune effector cell-

associated neurotoxicity (ICANS). Because of the risks of CRS and neurologic toxicity, including ICANS, talquetamab-tgvs is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS), called the Tecvayli-Talvey REMS.

The most common adverse reactions reported in the 339 patients in the safety population (≥ 20%) were CRS, dysgeusia, nail disorder, musculoskeletal pain, skin disorder, rash, fatigue, decreased weight, dry mouth, pyrexia, xerosis, dysphagia, upper respiratory tract infection, and diarrhea.

The recommended talquetamab-tgvs dose is either 0.4 mg/kg weekly or 0.8 mg/kg biweekly. See the prescribing information for the full dosing schedules.

This review was conducted under Project Orbis, an initiative of the FDA Oncology Center of Excellence. Project Orbis provides a framework for concurrent submission and review of oncology drugs among international partners. For this review, FDA collaborated with the Australian Therapeutic Goods Administration (TGA) and Switzerland's Swissmedic. The application reviews are ongoing at the other regulatory agencies.

This review used the Assessment Aid, a voluntary submission from the applicant to facilitate the FDA's assessment.

This application was granted priority review, breakthrough designation, and orphan drug designation. FDA expedited programs are described 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.

This announcement was published by the Food and Drug Administration on August 9, 2023.
