



Recall Alert

FDA approves teclistamab in combination with daratumumab hyaluronidase-fihj for relapsed or refractory multiple myeloma

An update on the Cyclospora outbreak available here (<https://www.fda.gov/food/outbreaks-foodborne-illness/investigation-5-state-outbreak-cyclospora-illnesses-iceberg-lettuce-july-2026>).

On March 5, 2026, the Food and Drug Administration approved teclistamab (Tecvayli, Janssen Biotech, Inc.) in combination with daratumumab hyaluronidase-fihj for adult patients with relapsed or refractory multiple myeloma who have received at least one prior line of therapy including a proteasome inhibitor and an immunomodulatory agent.

Today's approval also converts the accelerated approval to traditional approval for teclistamab, as monotherapy, in 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. Teclistamab received accelerated approval for this indication in 2022.

This application is part of the [FDA Commissioner's National Priority Review Voucher \(CNPV\) pilot program \(/industry/commissioners-national-priority-voucher-cnpv-pilot-program\)](#), which is designed to accelerate the review of products with the potential to address key national priorities.

Full prescribing information for Tecvayli will be posted on [Drugs@FDA](#) (<https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm>).

Efficacy and Safety

Efficacy was evaluated in MajesTEC-3 (NCT05083169), a randomized, open-label, multi-center trial. A total of 587 patients were randomized in the trial to the teclistamab and daratumumab hyaluronidase-fihj group (n=291) and to the investigator's choice control group of either daratumumab hyaluronidase-fihj, pomalidomide, and dexamethasone [DPd] or daratumumab hyaluronidase-fihj, bortezomib, and dexamethasone [DVd] (n=296).

The major efficacy outcome measure was progression-free survival (PFS) by independent review committee assessment based on International Myeloma Working Group 2016 criteria. Overall survival (OS) was an additional efficacy outcome measure. Median PFS was not reached (NR) (95% CI: NE, NE) in the teclistamab and daratumumab hyaluronidase-fihj arm

and was 18.1 months (95% CI: 14.6, 22.8) in the control arm (Hazard ratio 0.17 [95% CI: 0.12, 0.23]; p-value <0.0001). Median OS was NR (95% CI: NE, NE) and NR (95% CI: 41.4, NE) in the respective arms (Hazard ratio 0.46 [95% CI: 0.32, 0.65]; p-value <0.0001).

The prescribing information for Tecvayli includes a Boxed Warning for life threatening or fatal cytokine release syndrome (CRS) and neurologic toxicity, including immune effector cell-associated neurotoxicity (ICANS). Tecvayli is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS), called the Tecvayli-Talvey REMS.

In addition to CRS, the most common side effects of Tecvayli in combination with daratumumab hyaluronidase-fihj include hypogammaglobulinemia, upper respiratory tract infection, cough, diarrhea, musculoskeletal pain, COVID-19, pneumonia, injection site reaction, fatigue, pyrexia, headache, nausea, gastroenteritis, and decreased weight.

See the prescribing information for the recommended doses of teclistamab and daratumumab hyaluronidase-fihj.

This review was conducted under [Project Orbis \(/about-fda/oncology-center-excellence/project-orbis\)](/about-fda/oncology-center-excellence/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 Health Canada (HC) and Switzerland's Swissmedic (SMC). The applications may still be under review at the other regulatory agencies.

This review used the [Real-Time Oncology Review \(/about-fda/oncology-center-excellence/real-time-oncology-review-pilot-program\)](/about-fda/oncology-center-excellence/real-time-oncology-review-pilot-program) (RTOR) pilot program, which streamlined data submission prior to the filing of the entire clinical application, and the [Assessment Aid \(/about-fda/oncology-center-excellence/assessment-aid\)](/about-fda/oncology-center-excellence/assessment-aid), a voluntary submission from the applicant to facilitate the FDA's assessment.

Expedited Programs

This application was granted priority review. Teclistamab received breakthrough designation and orphan drug designation. FDA expedited programs are described in the [Guidance for Industry: Expedited Programs for Serious Conditions-Drugs and Biologics \(/regulatory-information/search-fda-guidance-documents/expedited-programs-serious-conditions-drugs-and-biologics\)](/regulatory-information/search-fda-guidance-documents/expedited-programs-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 \(https://www.accessdata.fda.gov/scripts/medwatch/index.cfm\)](https://www.accessdata.fda.gov/scripts/medwatch/index.cfm) 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 \(https://www.fda.gov/about-fda/oncology-center-excellence/project-facilitate\)](https://www.fda.gov/about-fda/oncology-center-excellence/project-facilitate) at 240-402-0004 or email OncProjectFacilitate@fda.hhs.gov (<mailto:OncProjectFacilitate@fda.hhs.gov>).

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