

FDA grants accelerated approval to dostarlimab-gxly for dMMR advanced solid tumors

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On August 17, 2021, the Food and Drug Administration granted accelerated approval to dostarlimab-gxly (Jemperli, GlaxoSmithKline LLC) for adult patients with mismatch repair deficient (dMMR) recurrent or advanced solid tumors, as determined by an FDA-approved test. This approval is based on the results of the GARNET Trial (NCT02715284), a non-randomized, multicenter, open-label, multi-cohort trial. The efficacy population consisted of 209 patients with dMMR recurrent or advanced solid tumors who progressed following systemic therapy and had no satisfactory alternative treatment.

Today, the FDA also approved the VENTANA MMR RxDx Panel as a companion diagnostic device to select patients with dMMR solid tumors for treatment with dostarlimab-gxly.

The efficacy of dostarlimab was evaluated in the GARNET Trial (NCT02715284), a non-randomized, multicenter, open-label, multi-cohort trial. The efficacy population consisted of 209 patients with dMMR recurrent or advanced solid tumors who progressed following systemic therapy and had no satisfactory alternative treatment.

The primary efficacy endpoints were overall response rate (ORR) and duration of response (DoR) as determined by blinded independent central review according to RECIST 1.1. The ORR was 41.6% (95% CI: 34.9, 48.6), with 9.1% complete response rate and 32.5% partial response rate. Median DOR was 34.7 months (range 2.6, 35.8+), with 95.4% of patients with duration ≥6 months.

Most common adverse reactions (≥20%) in patients with dMMR solid tumors are fatigue /asthenia, anemia, diarrhea, and nausea. Most common Grade 3 or 4 adverse reactions (≥2%) were anemia, fatigue/asthenia, increased transaminases, sepsis, and acute kidney injury. Immune-mediated adverse reactions are also associated with dostarlimab-gxly including pneumonitis, colitis, hepatitis, endocrinopathies, nephritis and dermatologic toxicity.

The recommended dostarlimab dosage is 500 mg every 3 weeks for dose 1 through 4, as an intravenous infusion over 30 minutes. Subsequent dosing beginning 3 weeks after dose 4 is 1,000 mg every 6 weeks.

[View full prescribing information for Jemperli.](#)

This indication is approved under accelerated approval based on tumor response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

This review used the [Assessment Aid](#), a voluntary submission from the applicant to facilitate the FDA's assessment.

This application was granted priority review. 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.

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IPR2024-00624

professionals may contact OCE's [Project Facilitate](#) at 240-402-0004 or email OncProjectFacilitate@fda.hhs.gov.

For information on the COVID-19 pandemic, see the following resources:

- [FDA: Coronavirus Disease 2019 \(COVID-19\)](#)
- [NCI: Coronavirus: What People With Cancer Should Know](#)
- [CDC: Coronavirus \(COVID-19\)](#)

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