RP1 gains FDA committee support for approval in melanoma

Market Event Summary

Pragati Tripathi | August 2026

FDA advisors voted 10-3 in favor of RP1 despite its previous regulatory setback in advanced melanoma

Background

- Vusolimogene oderparevec (RP1), an **intralesional HSV-1-based oncolytic immunotherapy,** is being **tested** with nivolumab in adults with **anti-PD-1-refractory advanced melanoma** and has received **BTD** in the United States.
- Despite **positive Phase 1/2 IGNYTE data** (ORR 33.6%, DOR 24.8 months, median OS 32.9 months, 3-year OS rate 47.8%), **Replimune's BLA's** received **two CRLs** (July 2025 and April 2026) **citing** concerns about the **interpretability of efficacy data** and **trial design.**
- **Following resubmitted BLA acceptance** in June 2026, the application underwent advisory committee review ahead of the **August 2, 2026,** goal date; meanwhile, the ongoing **Phase 3 IGNYTE-3 trial** is expected to provide **confirmatory** evidence of clinical benefit.

Event

- **FDA's Cellular, Tissue, and Gene Therapies Advisory Committee** (CTGTAC) **reviewed** Replimune's resubmitted **BLA for RP1 + nivolumab** in **anti-PD-1-refractory advanced melanoma**.
- The committee discussed the **reliability** and **clinical meaningfulness** of the **Phase 1/2 IGNYTE data**, including whether the observed responses and durability reflected systemic **antitumor activity** attributable to RP1.
- The committee **voted 10 to 3 in favor** of RP1, concluding that the efficacy results are evaluable and clinically meaningful.

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Clarivate's takeaways

Potential FDA approval could be imminent

The positive ODAC vote brings RP1 closer to FDA accelerated approval. As the first intralesional oncolytic immunotherapy, RP1 could offer a more accessible alternative to complex cell therapies while addressing a significant unmet need in the post-PD-1 setting.

Competitive pipeline in PD-1 refractory melanoma

Competition in anti-PD-1-refractory melanoma is intensifying, with TCR-T cell therapies, bispecific T-cell-engaging fusion proteins, and other novel therapies in development. If approved, RP1 + nivolumab will compete with approved TIL therapy and emerging treatments.

Phase 3 confirmation remains critical

While the advisory committee favored the available early-phase data, the ongoing Phase 3 IGNYTE-3 trial data against the relevant comparator will be necessary to definitively confirm clinical benefit. Consequently, long-term commercial uptake and physician confidence are likely to depend on successful Phase 3 outcomes and eventual validation of the survival benefit.

About the author

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Prior to joining Clarivate, Ms. Tripathi was a senior research associate in the intellectual property and research division at Evalueserve in Gurgaon. She conducted secondary research and delivered technology landscape reports in the domain of pharmaceutical sciences and healthcare. She obtained her master's degree in pharmaceutical chemistry from the Birla Institute of Technology and Science in Pilani.

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