

FDA approves Syndax / Incyte's Niktimvo, a first-in-class anti- CSF-1R antibody, for chronic graft versus host disease

Market Event Summary

Niktimvo becomes the second therapy approved for third-line treatment of chronic GVHD

Event

- On August 14, 2024, the FDA approved Syndax / Incyte's Niktimvo (axatilimab-csfr), a first-in-class anti-CSF-1R antibody therapy, for the treatment of chronic GVHD patients who have failed at least two lines of systemic therapy in adults and children weighing at least 40 kg, with an expected launch in Q1 2025.
- The approval, which came two weeks ahead of its PDUFA date, was based on results of the Phase 2 AGAVE-201 trial, with ORR of 75% in chronic GVHD patients treated with Niktimvo (0.3 mg/kg every two weeks).
- The drug is administered via IV infusion every two weeks.

Competition

- Sanofi's Rezurock (belumosudil), a ROCK2 inhibitor, had been the only approved treatment for chronic GVHD patients aged 12 or older who have failed at least two lines of systemic therapy. It was approved in the United States and United Kingdom in 2021 and 2022, respectively.
- The approval was based on results of the Phase 2 ROCKstar trial, with ORR of 75% in chronic GVHD patients treated with Rezurock.
- The drug is administered orally once daily.

Clarivate's takeaways



Treatment dynamics

Rezurock and Niktimvo will be direct competitors because of the similarity in their FDA labels. Rezurock's first-mover advantage, convenient oral dosing, and established efficacy will be influential in its market performance.

- The FDA's approval of Rezurock for third-line chronic GVHD provided a much-needed option for these underserved patients. With the approval of Niktimvo, treatment options for third-line chronic GVHD patients will be expanded.
- Interviewed KOLs consider both Rezurock and Niktimvo to be very promising drugs that have similar efficacy. However, most of them indicated that Rezurock would be the preferred treatment option for third-line chronic GVHD because of its established market presence and convenient oral dosing.



Commercial

Based on the optimism of interviewed KOLs and Niktimvo's encouraging efficacy data in clinical trials, and despite the IV dosing, we expect Niktimvo to garner sales of \$70 million in the United States in 2033 for third-line chronic GVHD. Additionally, we expect the approval of Niktimvo in the EU5 for the same population setting by 2025, garnering sales of \$19 million in 2033.

About the author



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