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Sanofi’s Rezurock receives approval in India for treating patients with chronic graft-versus-host disease

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A life-threatening complication that can occur in 35-40% patients after bone marrow transplant

Sanofi Healthcare India has announced receipt of marketing authorisation for Rezurock (Belumosudil Tablets) in India. Rezurock represents a new, best-in-class treatment paradigm for thousands of cGVHD patients globally (12 years and above), after failure of two previous lines of treatment, including those with difficult-to-treat manifestations like fibrosis.

Rezurock was approved by the US FDA (in 2021) and by the CDSCO in India (in 2024) based on safety and efficacy results from ROCKstar – a randomised, open-label, multicenter pivotal trial of Rezurock in patients with cGVHD who had received two to five prior lines of systemic therapy.

Administered once daily (orally), Rezurock 200 mg achieved an Overall Response Rate (ORR) of 74% and has shown robust and durable responses across the spectrum of cGVHD. It is safe and well-tolerated with adverse events being consistent to those expected in patients with advanced cGVHD receiving corticosteroids and/or other immunosuppressants.

Rodolfo Hrosz, Managing Director, Sanofi India Limited, said “cGVHD has a debilitating impact on the day-to-day functioning of those suffering from it. Treatment options for people suffering from it are very limited. This milestone reflects our dedication to addressing unmet medical needs in the transplant ecosystem and delivering breakthrough therapies for patients with this severe condition."