

## *Sanofi's breakthrough therapy Rezurock® approved in India for treating patients living with chronic graft-versus-host disease (cGVHD)*

*cGVHD is a life-threatening complication that can occur in 35-40% patients after bone marrow transplant<sup>i</sup>*

**Mumbai, February 10, 2025.** Sanofi Healthcare India Pvt. Limited announces receipt of marketing authorization 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<sup>ii</sup> (in 2021) and by the CDSCO<sup>iii</sup> in India (in 2024) based on safety and efficacy results from ROCKstar – a randomized, 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)<sup>iv</sup> 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

*“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. The introduction of Rezurock® reinforces Sanofi India's leadership in the field of immunology and transplant care.”*

### **About chronic graft-versus-host disease**

cGVHD is a complication that can occur following allogeneic stem cell transplantation, resulting in significant morbidity and mortality. In cGVHD, transplanted immune cells (graft) attack the patient's cells (host), leading to inflammation and fibrosis in multiple tissues, including skin, mouth, eye, joints, liver, lung, esophagus and gastrointestinal tract.

Sanofi remains committed to collaborating with healthcare professionals and stakeholders to ensure Rezurock® is accessible to patients across India.

### ***Sanofi in India***

Present in India for nearly seven decades, Sanofi has earned the trust of customers and stakeholders for its commitment to promoting health. As Sanofi chases the miracles of science to improve people's lives, it continues to engage across the entire health spectrum from prevention with vaccines to wellness, treatment, patient support & capacity building.

Sanofi's India Charitable Access Program (InCAP) is the country's longest running humanitarian program providing free treatment to people afflicted with Lysosomal Storage Disorders. Sanofi conducts clinical trials in India, so that the country can have quicker access to the latest from the company's global pipeline. Sanofi India's world-class manufacturing site in Goa produces for people in India and 60+ other countries. Sanofi has located one of its four global talent hubs in Hyderabad, India, from where wide range of services are provided globally.

Recognized by the 'Top® Employers Institute' – a global authority that honours excellence in

people practices since 2019, Sanofi's local entities include Sanofi India Limited (SIL - listed entity), and Sanofi Healthcare India Pvt. Ltd. (SHIPL) and Sanofi Consumer Healthcare India Limited (SCHIL). For more information, visit: [www.sanofi.in](http://www.sanofi.in) and [www.sanofiindialtd.com](http://www.sanofiindialtd.com), [LinkedIn](#) and [Twitter](#).

### **About Sanofi**

About Sanofi We are an innovative global healthcare company, driven by one purpose: we chase the miracles of science to improve people's lives. Our team, across the world, is dedicated to transforming the practice of medicine by working to turn the impossible into the possible. We provide potentially life-changing treatment options and life-saving vaccine protection to millions of people globally, while putting sustainability and social responsibility at the center of our ambitions.

Sanofi is listed on Euronext: SAN and NASDAQ: SNY

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<sup>i</sup> Biju George et Al. Haploidentical transplantation is feasible and associated with reasonable outcomes despite major infective complications - A single center experience from India. *Transplantation and Cellular Therapy* 28 (2022) 45.e1 - 45.e8, Sachin Punatar et Al. Chronic Graft Versus Host Disease in Acute Leukemia Patients Undergoing Allogeneic Hematopoietic Stem Cell Transplant: Analysis of Risk Factors, Pattern and Long-Term Outcome. *Indian J Hematol Blood Transfus* (Jan-Mar 2016) 32(1):32-38

<sup>ii</sup> United States Food Drug Administration

<sup>iii</sup> Central Drugs Standard Control Organisation

<sup>iv</sup> Overall response rate = complete response rate + partial response rate