

## *Sanofi's Rezurock approved in the EU to treat chronic graft-vs-host disease*

- Rezurock is now approved in the EU for adults and children aged 12 years and older with chronic GVHD, providing a new medicine for patients with limited treatment options

**Paris, March 31, 2026.** The European Commission has granted a conditional marketing authorisation for Rezurock (belumosudil) for the treatment of chronic graft-versus-host disease (GVHD) in adults and in children aged 12 years and older with a body weight of at least 40 kg. The medicine is to be used when other treatment options provide limited clinical benefit, are not suitable, or have been exhausted. The conditional marketing authorisation is contingent on completion of a confirmatory, randomised, controlled study. This follows the [positive opinion](#) by the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) issued on 30 January 2026.

*"Chronic GVHD is a serious and potentially life-threatening condition, imposing profound physical and emotional burdens on a substantial proportion of patients following allogeneic stem cell transplantation. Across the EU, many patients continue to face significant challenges in managing this disease, particularly when existing therapies fail to provide adequate benefit,"* said **Mohamad Mohty**, Professor of Haematology and Head of the Haematology and Cellular Therapy Department at Hôpital Saint-Antoine and Sorbonne University, Paris, France. *"This approval represents an important advance, offering a new therapeutic option that has the potential to meaningfully improve the lives of patients."*

*"Nearly one in two patients with chronic GVHD require third-line treatment, yet therapeutic options available for EU patients at this late stage of the disease have remained limited,"* said **Olivier Charmeil**, Executive Vice President, General Medicines, and Interim CEO, Sanofi. *"We have an ongoing commitment to supporting patients with chronic GVHD and their caregivers and are pleased to deliver this new treatment option to patients living with this debilitating and long-term condition."*

This approval is based on safety and efficacy results from several clinical studies and real-world evidence. This includes the randomised, multicenter ROCKstar phase 2 study (clinical study identifier: [NCT03640481](#)), which demonstrated clinically meaningful and durable responses with Rezurock in patients living with chronic GVHD after stem cell transplant and at least two prior lines of systemic therapy. Treatment was generally well tolerated. Under the conditional marketing authorisation, Sanofi will conduct a new, confirmatory, randomised, controlled study.

The medicine was designated 'orphan' (a medicine used in rare diseases) in 2019 for the treatment of graft-versus-host disease. Following this conditional marketing authorisation, the Committee for Orphan Medicinal Products (COMP) of the European Medicines Agency has also formally adopted an opinion on the maintenance of orphan designation.

In addition to the EU, Rezurock is approved in 20 countries, including the US, UK, and

Canada for the treatment of patients 12 years and older with chronic GVHD after failure of at least two prior lines of systemic therapy, and in China after failure of one prior line of systemic therapy.

More than 20,000 patients living with chronic GVHD have been treated with Rezurock since its first approval in the US in July 2021.

#### *About Rezurock*

Rezurock (belumosudil) is a selective ROCK2 (rho-associated coiled-coil kinase 2) inhibitor. It has been shown to help many different types of people with chronic GVHD after failure of any two other types of treatment.

Sanofi is committed to assessing the safety and efficacy of Rezurock in other age groups and indications, including through ongoing studies for paediatric patients with chronic GVHD from one year old who have been treated with at least two prior lines of systemic therapy and for patients with chronic lung allograft dysfunction. These additional indications are currently in clinical studies and have not been approved by regulatory authorities.

#### *About the ROCKstar study*

ROCKstar was a pivotal phase 2, open label, non-controlled, randomised, multicentre study that evaluated the efficacy and safety of Rezurock in patients with chronic GVHD after receiving two to five prior lines of systemic therapy. A three-year, open-label, follow-up analysis of the ROCKstar study evaluated the long-term efficacy of Rezurock.

Treatment consisted of Rezurock 200 mg and was administered continuously until clinically significant progression of chronic GvHD or unacceptable toxicity. The primary endpoint was best overall response rate (ORR) at any time.

Study results demonstrated clinically meaningful and statistically significant best ORR of 74% on treatment with Rezurock (n=77, 95% CI, 63-83 p<0.0001). The most common adverse reactions were fatigue (46%), diarrhoea (35%), nausea (35%), dyspnoea (32%), cough (30%) and upper respiratory tract infections (26%).

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

GVHD is a life-threatening complication that can occur following stem cell transplant (or allogeneic hematopoietic stem cell transplant) where the donor's (graft) cells attack the host's cells, leading to inflammation and fibrosis (scarring or thickening) that can damage multiple tissues and organs. Chronic GVHD devastates the lives of up to 50% of patients who undergo an allogeneic hematopoietic stem cell transplant. GVHD is considered one of the main causes of morbidity (poor health) and late non-relapse mortality after stem cell transplant. The consequences are far-reaching, both in terms of the burden it can place on the individual's physical and emotional well-being, as well as the broader socio-economic impact.

#### *About Sanofi*

Sanofi is an R&D driven, AI-powered biopharma company committed to improving people's lives and delivering compelling growth. We apply our deep understanding of the immune system to invent medicines and vaccines that treat and protect millions of people around the world, with an innovative pipeline that could benefit millions more. Our team is guided by one purpose: we chase the miracles of science to improve people's lives; this inspires us to drive progress and deliver positive impact for our people and the communities we serve, by addressing the most urgent healthcare, environmental, and societal challenges of our time. Sanofi is listed on Euronext: SAN and NASDAQ: SNY

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