Press Release

Sanofi's Rezurock recommended for EU approval by the CHMP to treat chronic graft-vs-host disease

- Recommendation supported by safety and efficacy results from several clinical studies and real-world evidence
- If approved, Rezurock would offer a new treatment option in the EU for adult patients and in children aged 12 years and older in late line chronic GVHD

Paris, January 30, 2026. The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has adopted a positive opinion recommending the conditional marketing authorisation of Rezurock (belumosudil) in the EU for the treatment of adults and in children aged 12 years and older with a body weight of at least 40 kg, with chronic graft-versus-host disease (GvHD). The medicine is to be used when other treatment options provide limited clinical benefit, are not suitable, or have been exhausted. This positive recommendation comes after Sanofi requested a re-examination of the prior negative opinion adopted by the CHMP in October 2025. The final European Commission decision is expected in the coming weeks.

> *"Chronic GVHD can involve multiple organs and profoundly affect patients' daily lives, limiting everyday activities and taking a substantial emotional toll,"* said **Prof Mohamad Mohty,** Professor of Haematology, Head of the Haematology and Cellular Therapy Department at Hôpital Saint-Antoine and Sorbonne University, Paris, France. *"For patients who have exhausted available treatment options, this positive opinion marks an important step forward in our ability to better manage this challenging disease."*
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> *"We sought a re-examination of the CHMP opinion, and made the commitment to conduct a new post-approval confirmatory study, given the limited late-line treatment options available for EU patients living with chronic GVHD and the body of Rezurock clinical evidence generated including data from patients in Europe,"* said **Olivier Charmeil**, Executive Vice President, General Medicines, Sanofi. *"We remain committed to supporting the GVHD community and welcome this positive CHMP opinion, which brings us closer to delivering a new approved treatment in the EU for adult and adolescent GVHD patients who are waiting."*

This CHMP recommendation is based on safety and efficacy results from several clinical studies and real-world evidence. This includes the randomised, multicentre ROCKstar phase 2 study, which demonstrated clinically meaningful and durable responses with Rezurock for 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 CHMP positive opinion for conditional marketing authorisation, Sanofi will also conduct a confirmatory randomised controlled study.

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 17,000 patients living with chronic GVHD have been treated with Rezurock in approved countries since its first approval in the US in July 2021.

About Rezurock

Rezurock (belumosudil) is Sanofi's first-in-class selective ROCK2 (Rho-associated coiled-

coil kinase 2) inhibitor (ROCK2i). 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 investigating 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 under investigation 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 2 to 5 prior lines of systemic therapy. A 3-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). 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 creating 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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