Press Release

Sanofi provides update on regulatory review in the EU for Rezurock to treat chronic graft-vs-host disease

Paris, October 17, 2025. The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has issued a negative opinion on the marketing authorisation application for Rezurock (belumosudil) for the third-line treatment of adults and pediatric patients with chronic graft-versus-host disease (cGVHD). Sanofi will seek a re-examination of the CHMP opinion.

cGVHD is a life-threatening complication that devastates the lives of up to 50% of patients who undergo a stem cell transplant. cGVHD is considered one of the main causes of morbidity and late non-relapse mortality after stem cell transplant.

> "*We are disappointed by the negative CHMP opinion for Rezurock in the EU and remain committed to serving the transplant patient community*," said **Olivier Charmeil**, Executive Vice President, General Medicines at Sanofi. "*Sanofi is confident in the body of clinical and real-world evidence that underscores Rezurock's consistent efficacy and well-established safety profile for treating third-line chronic graft-versus-host disease. We will continue to work closely with the European Medicines Agency with the aim of bringing this treatment to patients in the EU who are waiting.*"

Rezurock is supported by safety and efficacy results from several clinical studies and real-world evidence. This includes the randomized, multicenter ROCKstar phase 2 study, that demonstrates consistent efficacy and tolerability for patients living with cGVHD after stem cell transplant as well as durable clinical responses over a period of three years.

Rezurock is currently approved in 20 countries, including the US, UK and Canada for the treatment of patients 12 years and older with cGVHD 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 cGVHD worldwide have been prescribed Rezurock since its first approval in the US in July 2021.

About Rezurock

Rezurock (belumosudil) is a first-in-class selective ROCK2 (Rho-associated coiled-coil kinase 2) inhibitor (ROCK2i).

Sanofi is committed to investigating the benefits of Rezurock in other age groups and indications, including through ongoing studies for pediatric patients with cGVHD 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.

About chronic graft-versus-host disease

GVHD is a 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 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

Media Relations

Sandrine Guendoul | +33 6 25 09 14 25 | sandrine.guendoul@sanofi.com
Evan Berland | +1 215 432 0234 | evan.berland@sanofi.com
Léo Le Bourhis | +33 6 75 06 43 81 | leo.lebourhis@sanofi.com
Victor Rouault | +33 6 70 93 71 40 | victor.rouault@sanofi.com
Timothy Gilbert | +1 516 521 2929 | timothy.gilbert@sanofi.com
Léa Ubaldi | +33 6 30 19 66 46 | lea.ubaldi@sanofi.com

Investor Relations

Thomas Kudsk Larsen | +44 7545 513 693 | thomas.larsen@sanofi.com
Alizé Kaisserian | +33 6 47 04 12 11 | alize.kaisserian@sanofi.com
Felix Lauscher | +1 908 612 7239 | felix.lauscher@sanofi.com
Keita Browne | +1 781 249 1766 | keita.browne@sanofi.com
Nathalie Pham | +33 7 85 93 30 17 | nathalie.pham@sanofi.com
Tarik Elgoutni | +1 617 710 3587 | tarik.elgoutni@sanofi.com
Thibaud Châtelet | +33 6 80 80 89 90 | thibaud.chatelet@sanofi.com
Yun Li | +33 6 84 00 90 72 | yun.li3@sanofi.com