company announcement

Etavopivat is the first in a new class of drugs to successfully meet both co-primary endpoints in the phase 3 HIBISCUS trial, substantially reducing vaso-occlusive crisis events and improving haemoglobin response in sickle cell disease

- Etavopivat showed a 27% reduction in vaso-occlusive crisis events and ~4-month delay to first vaso-occlusive crisis event on top of standard of care[1]
- Haemoglobin response was superior with etavopivat: 48.7% of people on treatment achieved an increase of >1g/dL after 24 weeks versus 7.2% on placebo[1]
- Novo Nordisk plans to submit for the first regulatory approval of etavopivat in the second half of 2026

Bagsværd, Denmark, 20 April 2026 – Novo Nordisk today announced the topline results from HIBISCUS, a pivotal phase 3 trial of once-daily oral etavopivat in adults and adolescents with sickle cell disease (SCD). The results showed that etavopivat successfully met both co-primary endpoints, demonstrating superior reduction in vaso-occlusive crises (VOCs) and superior improvement in haemoglobin (Hb) response compared to placebo.

Etavopivat is an oral, once-daily, pyruvate kinase-R (PKR) activator being developed to treat SCD, a seriously debilitating, life-threatening and life-shortening disease that impacts around 8 million people worldwide.

The HIBISCUS trial was a randomised, double-blinded, 52-week efficacy and safety trial investigating etavopivat 400 mg versus placebo in 385 people aged 12 years or older with SCD. Participants were allowed to receive standard of care treatment throughout the trial.

In the trial[1], people treated with etavopivat demonstrated a superior reduction in the annualised rate of VOCs of 27% compared to placebo. The time to first VOC was significantly

[1] Primary analysis of VOC based on negative binomial regression model with exposure time as offset variable. Primary analysis of Hb response based on exact Cochran-Mantel-Haenszel test with missing data ascribed as non-responders. Time to VOC based on Kaplan-Meier estimates and a stratified log-rank test.

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prolonged with etavopivat, with a median time to first VOC of 38.4 weeks versus 20.9 weeks for placebo.

In addition, etavopivat demonstrated a superior increase in the proportion of people achieving a Hb response greater than 1g/dL at week 24 of 48.7% compared to 7.2% with placebo, corresponding to an adjusted rate difference of 41.2%[1]. Further, as an exploratory analysis, etavopivat significantly reduced the risk of blood transfusion.

In the trial, etavopivat appeared to be well tolerated, with a topline safety profile in line with previous etavopivat trials.

"Sickle cell disease severely impacts the lives of millions of people. We are very excited that etavopivat has the potential to be a first and best-in-class therapy and transform the lives of people with sickle cell disease, who currently have limited therapeutic options," said Martin Holst Lange, executive vice president, chief scientific officer and head of Research and Development at Novo Nordisk. "Novo Nordisk remains committed to collaborating with sickle cell disease communities around the world to drive innovation, advance health equity and improve access to treatment and care."

Novo Nordisk plans to submit for the first regulatory approval of etavopivat in the second half of 2026. The detailed results from the HIBISCUS phase 3 trial will be presented at a scientific conference in 2026.

About Sickle Cell Disease

Sickle cell disease (SCD) is a group of diseases driven by polymerisation of mutated sickle haemoglobin (HbS) in red blood cells. The two main hallmarks of SCD are haemolytic anaemia and vaso-occlusive crises (VOCs). Around 8 million people worldwide live with SCD, with the majority in low and middle-income countries. Approximately 100,000 people living with SCD are in the United States, as well as approximately 110,000 in Europe. The disease is characterised by several associated acute and chronic symptoms and complications such as acute chest syndrome, stroke, altered cerebral blood flow, multi-organ damage, and cognitive impairment. Despite recent advances in treatment, many people with SCD experience significant levels of pain and reduced lifespan by approximately 30 years compared to the general population.

About etavopivat

Etavopivat is a once-daily orally available small molecule allosteric activator of red blood cell (RBC) pyruvate kinase isozyme (PKR), a key enzyme in glycolysis. In SCD, PKR activation reduces 2,3-diphosphoglycerate (2,3-DPG) levels and increases adenosine triphosphate (ATP) production. Reduction of 2,3-DPG improves haemoglobin (Hb)-oxygen affinity, averting sickle haemoglobin polymerisation and subsequent sickling. The increase in ATP production helps

preserve RBC membrane integrity and deformability, improving RBC survival. These disease-modifying effects have the potential to reduce VOC events and improve Hb levels.

The U.S. Food and Drug Administration (FDA) has granted etavopivat Fast Track, Rare Pediatric Disease and Orphan Drug designations. Additionally, etavopivat was granted Orphan Drug designation by the European Commission based on a positive opinion from the Committee for Orphan Medicinal Products of the European Medicines Agency for the treatment of patients with SCD.

Etavopivat was acquired as part of the 2022 acquisition of Forma Therapeutics.

About the HIBISCUS programme
The HIBISCUS clinical development programme investigates etavopivat as a disease-modifying treatment for people with SCD, with standard of care/placebo. The pivotal programme includes:

HIBISCUS - a 52-week efficacy and safety seamless, adaptive design phase 2/3 trial, comparing once-daily etavopivat versus standard of care/placebo, enrolling 440 people aged 12 years and over with SCD. Following the completion of the 12-week phase 2 interim read-out, the phase 3 dose was selected, and participants were randomised to the phase 3 main phase of the trial, which continued for 52 weeks.

HIBISCUS2 - a 52-week efficacy and safety phase 3b trial, comparing once-daily etavopivat versus standard of care/placebo, enrolling 408 people aged 12 years and over with SCD.

FLORAL – an open-label extension following participation in etavopivat trials. The study allows the collection of long-term safety data.

About Novo Nordisk

Novo Nordisk is a leading global healthcare company founded in 1923 and headquartered in Denmark. Our purpose is to drive change to defeat serious chronic diseases built upon our heritage in diabetes. We do so by pioneering scientific breakthroughs, expanding access to our medicines and working to prevent and ultimately cure disease. Novo Nordisk employs about 68,800 people in 80 countries and markets its products in around 170 countries. Novo Nordisk's B shares are listed on Nasdaq Copenhagen (Novo-B). Its ADRs are listed on the New York Stock Exchange (NVO). For more information, visit novonordisk.com, Facebook, Instagram, X, LinkedIn and YouTube.

Publication of inside information pursuant to Market Abuse Regulation, Article 17.

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