

Press release

Stockholm, Sweden, 16 January 2026

Sobi Receives European Commission Approval for Aspaveli® (pegcetacoplan) for the Treatment of C3G and Primary IC-MPGN

- *Approximately 8,000 people in Europe are living with C3G or primary IC-MPGN*
- *Aspaveli (pegcetacoplan) is the first treatment of primary IC-MPGN and the first treatment for C3G and primary IC-MPGN for patients 12 years and older*

Sobi® (STO: SOBI), today announced that the European Commission (EC) has approved Aspaveli® (pegcetacoplan) for the treatment of adult and adolescent patients aged 12 to 17 years with C3 glomerulopathy (C3G) or primary immune-complex membranoproliferative glomerulonephritis (IC-MPGN) in combination with a renin-angiotensin system (RAS) inhibitor, unless RAS inhibitor treatment is not tolerated or contraindicated

The approval follows a positive opinion from the Committee for Medicinal Products for Human Use (CHMP) in December 2025. Aspaveli is a targeted C3/C3b inhibitor designed to regulate excessive complement activation, a key driver of C3G and primary IC-MPGN. These conditions are associated with progressive kidney damage and limited treatment options.

“The European Commission approval for Aspaveli represents an important milestone for people living with C3G or primary IC-MPGN in Europe, two severe and rare kidney diseases with limited treatment options and a high risk of progression to kidney failure,” said Lydia Abad-Franch, MD, Head of R&D and Medical Affairs, and Chief Medical Officer at Sobi. “This approval is underpinned by robust clinical evidence from the VALIANT trial, which demonstrated that pegcetacoplan is able to preserve kidney function by reducing proteinuria, stabilising eGFR and clearing C3 deposits. Aspaveli is now available for patients 12 years and older with these serious conditions. It is the first approved therapy for adolescent patients (12 to 17 years) and the first treatment indicated for primary IC-MPGN.”

C3G and primary IC-MPGN are rare kidney diseases affecting approximately 8,000 patients in Europe. More than half of people living with C3G or primary IC-MPGN suffer from kidney failure within five to 10 years of diagnosis, requiring a burdensome kidney transplant or dialysis therapy.¹⁻³

This approval is based on positive results from the Phase 3 VALIANT study, in which Aspaveli demonstrated benefits across the three key markers of disease, including significant reduction in proteinuria, stabilisation of kidney function, and substantial clearance of C3 deposits. These positive results were recently published in [The New England Journal of Medicine](#).⁶ Sobi and its partner Apellis Pharmaceuticals, Inc. have global co-development rights for systemic pegcetacoplan.

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About C3 Glomerulopathy (C3G) and Primary Immune-Complex Membranoproliferative Glomerulonephritis (IC-MPGN)

C3G and primary IC-MPGN are rare and debilitating kidney diseases that can lead to kidney failure. Excessive C3 deposits are a key marker of disease activity, which can lead to kidney inflammation, damage, and failure. Approximately 50% of people living with C3G or primary IC-MPGN suffer from kidney failure within five to 10 years of diagnosis, requiring a burdensome kidney transplant or dialysis therapy.¹⁻³ Additionally, approximately 90% of patients who previously received a kidney transplant will experience disease recurrence.⁴ The diseases are estimated to affect 5,000 people in the United States and up to 8,000 in Europe.⁵

About the VALIANT Study

The VALIANT Phase 3 study (NCT05067127) was a randomised, placebo-controlled, double-blinded, multi-center study that evaluated pegcetacoplan efficacy and safety in 124 patients who were 12 years of age and older with C3G or primary IC-MPGN. It is the largest single trial conducted in these populations and the only study to include paediatric and adult patients, with native and post-transplant kidneys. Study participants were randomised to receive pegcetacoplan or placebo twice weekly for 26 weeks. Following this 26-week randomised controlled period, patients were able to proceed to a 26-week open-label phase in which all patients received pegcetacoplan. The primary endpoint of the study was the log transformed ratio of urine protein-to-creatinine ratio (UPCR) at Week 26 compared to baseline.

About Aspaveli®/Empaveli® (pegcetacoplan)

Aspaveli/Empaveli (pegcetacoplan) is a targeted C3 and C3b therapy designed to regulate excessive activation of the complement cascade, part of the body's immune system, which can lead to the onset and progression of many serious diseases. It is the first treatment for C3 glomerulopathy (C3G) or primary immune complex membranoproliferative glomerulonephritis (IC-MPGN) in patients 12 years of age and older approved in the United States, European Union, and other countries globally.

Aspaveli/Empaveli is also approved for the treatment of adults with paroxysmal nocturnal haemoglobinuria (PNH) in the United States, European Union, and other countries globally.

About the Sobi® and Apellis Collaboration

Apellis and Sobi have global co-development rights for systemic pegcetacoplan. Sobi has exclusive ex-U.S. commercialisation rights for systemic pegcetacoplan. Apellis has exclusive U.S. commercialisation rights for systemic pegcetacoplan and worldwide commercial rights for ophthalmological pegcetacoplan, including for geographic atrophy.

Sobi®

Sobi is a global biopharma company unlocking the potential of breakthrough innovations, transforming everyday life for people living with rare diseases. Sobi has approximately 1,900 employees across Europe, North America, the Middle East, Asia and Australia. In 2024, revenue amounted to SEK 26 billion. Sobi's share (STO:SOBI) is listed on Nasdaq Stockholm. More about Sobi at sobi.com and [LinkedIn](https://www.linkedin.com/company/sobi).

Contacts

For details on how to contact the Sobi Investor Relations Team, please click [here](#). For Sobi Media contacts, click [here](#).

References

1. Smith RJH, et al. Nat Rev Nephrol. 2019;15(3):129-143.
2. Servais A, et al. Kidney Int. 2012;82(4):454-464.
3. Zand L, et al. J Am Soc Nephrol. 2014;25(5):1110-1117.
4. Tarragón, B, et al. Clin J Am Soc Nephrol 2024; 19(8)1005-1015.
5. Data on file using literature consensus.
6. Fakhouri F, et al. N Engl J Med 2025;393:2210-2220

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