Press release

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The New England Journal of Medicine Publishes Positive Phase 3 VALIANT Results of pegcetacoplan for C3G and Primary IC-MPGN

- *Robust and clinically meaningful benefits observed across all three key markers of disease – 68% reduction in proteinuria, stabilisation of kidney function, and substantial clearance of C3 deposits*

- *Consistent results across C3G and primary IC-MPGN, adults and adolescents, and native and post-transplant kidney disease*

- *Pegcetacoplan is under regulatory review for the treatment of C3G and primary IC-MPGN by EMA and other regulatory bodies.*

Sobi® (STO:SOBI) today announced that The New England Journal of Medicine (NEJM) published positive results from the Phase 3 VALIANT study investigating pegcetacoplan for C3 glomerulopathy (C3G) and primary immune complex membranoproliferative glomerulonephritis (IC-MPGN), which are severe and rare kidney diseases.

“Pegcetacoplan has demonstrated substantial and clinically meaningful effects across all three key markers of disease: proteinuria reduction, eGFR stabilisation, and clearance of C3 deposits. Given the high risk of kidney failure, the need for dialysis and kidney transplant, these data are a welcome advance for patients with C3G and primary IC-MPGN,” said Fadi Fakhouri, M.D., PhD., Professor of Nephrology from the University of Lausanne, and lead author of the manuscript.

The data published in NEJM highlights the positive Phase 3 VALIANT results at Week 26, which were consistent across patients with C3G and primary IC-MPGN, adolescents and adults, and native and post-transplant kidney disease.

- **Proteinuria reduction:** The study met its primary endpoint, demonstrating a statistically significant 68% ($p<0.0001$) proteinuria reduction in pegcetacoplan-treated patients compared to placebo
- **Stabilisation of kidney function:** Pegcetacoplan-treated patients achieved stabilisation of kidney function, with a difference of +6.3 mL/min/1.73 m^2 compared to placebo (nominal $p=0.03$) as measured by estimated glomerular filtration rate (eGFR)
- **Reduction of C3 staining:** A majority of pegcetacoplan-treated patients achieved a reduction in C3 staining intensity (nominal $p<0.0001$) with 71% of pegcetacoplan-

treated patients achieved zero C3 staining intensity, demonstrating complete clearance of C3 deposits.

Pegcetacoplan showed favourable safety and tolerability in the VALIANT study, consistent with its established profile.

Lydia Abad-Franch, MD, MBA, Head of Research, Development, and Medical Affairs (RDMA) and Chief Medical Officer at Sobi said, "The Phase 3 VALIANT data show the potential of pegcetacoplan for patients with C3G or primary IC-MPGN with consistent efficacy in both diseases and across patient groups, including adolescents and young adults where the conditions are most prevalent. We submitted the indication extension to the European Medicines Agency at the beginning of the year and hope to offer this new option to patients in Europe soon."

Results from the VALIANT study at one year were recently presented at the European Renal Association (ERA) Congress and American Societry of Nephrology (ASN) Kidney Week, showing sustained improvements in key markers of disease as well as favourable safety and tolerability.

An opinion from the Committee for Medicinal Products for Human Use (CHMP) is expected before year-end in the European Union**.**

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 and primary IC-MPGN suffer from kidney failure within five to 10 years of diagnosis, requiring a burdensome kidney transplant or lifelong 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 the efficacy and safety of pegcetacoplan 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 adolescent and adult patients with native or 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 Pegcetacoplan in Rare Diseases
Pegcetacoplan is a targeted C3 and C3b inhibitor 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 approved for paroxysmal nocturnal haemoglobinuria (PNH) as Aspaveli/EMPAVELI® in the United States, European Union, and other countries globally, and for C3 glomerulopathy (C3G) and primary immune complex membranoproliferative glomerulonephritis (IC-MPGN) in the United States.

About the Sobi and Apellis Collaboration
Sobi and Apellis have global co-development rights for systemic pegcetacoplan. Sobi has exclusive ex-U.S. commercialisation rights for systemic pegcetacoplan, and 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.

Contacts
For details on how to contact the Sobi Investor Relations Team, please click here. For Sobi Media contacts, click here.

References
1. Data on file using literature consensus.
2. Smith RJH, et al. *Nat Rev Nephrol*. 2019;15(3):129-143.
3. Servais A, et al. *Kidney Int*. 2012;82(4):454-464.
4. Zand L, et al. *J Am Soc Nephrol*. 2014;25(5):1110-1117.
5. Tarragón, B, et al. C3 Glomerulopathy Recurs Early after Kidney Transplantation in Serial Biopsies Performed within the First 2 Years after Transplantation. Clinical Journal of the American Society of Nephrology. August 2024; 19(8)1005-1015. doi: 10.2215/CJN.0000000000000474.