PRESS RELEASE
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Sobi and Apellis: Aspaveli®/Empaveli® Demonstrates Sustained One-Year Efficacy in Phase 3 Study for Rare Kidney Diseases

- *Robust proteinuria reduction and stable kidney function were maintained across a broad population of patients*
- *No new safety signals were observed*
- *New data presented at late-breaking session at the European Renal Association Congress*
- *Marketing applications for Aspaveli/Empaveli are under review with EMA and the FDA*

Sobi® (STO: SOBI) and Apellis Pharmaceuticals, Inc. today presented new data from the open-label period of the Phase 3 VALIANT study, investigating Aspaveli® (pegcetacoplan) for C3 glomerulopathy (C3G) and primary immune complex membranoproliferative glomerulonephritis (IC-MPGN).The data were presented as part of a late-breaking session at the European Renal Association (ERA) Congress.

In the VALIANT study, Aspaveli demonstrated a statistically significant 68% proteinuria reduction versus placebo at Week 26, which was sustained at one year. Additionally, patients treated with Aspaveli continued to achieve stabilization of kidney function as measured by estimated glomerular filtration rate (eGFR).

“The one-year Phase 3 results are very compelling, confirming Aspaveli’s sustained benefits across key markers of disease,” said Fadi Fakhouri, M.D., PhD, presenting author, co-lead principal investigator for the VALIANT study, and professor of nephrology at CHUV Lausanne, Switzerland. “Given the high risk of kidney failure, treatment efficacy is incredibly important to C3G and primary IC-MPGN patients, many of whom are in the prime of their lives. These data further underscore the potential of Aspaveli to make a meaningful difference for patients.”

In patients who switched from placebo to Aspaveli at the start of the open-label period, Aspaveli demonstrated a similar magnitude of benefit in proteinuria reduction and stabilization of kidney function.

Nils Kinnman, MD, PhD, Head of Medical Affairs and Clinical Development at Sobi said, “The results from the Phase 3 VALIANT study underscore the potential of Aspaveli in addressing the urgent needs of patients living with the kidney diseases C3G and primary IC-MPGN. This study is an example of Sobi’s commitment to advance innovative therapies that make a meaningful difference in patients' lives.”

“These data reinforce the strength of the EMPAVELI efficacy and safety profile across a broad population of patients with C3G and primary IC-MPGN, including adults and adolescents with native and post-transplant kidney disease,” said Peter Hillmen, M.B., Ch.B.,

Ph.D., chief medical advisor, rare disease, Apellis. “With an FDA decision this summer, we look forward to bringing EMPAVELI to patients living with these rare and severe kidney diseases as quickly as possible.”

EMPAVELI/Aspaveli showed favorable safety and tolerability, consistent with its established profile. There were no new safety signals.

Eight presentations highlight substantial clinical advances in rare kidney disease
A total of eight presentations, including six on podium, will be highlighted at the meeting. The presentations will showcase clinically meaningful results from the Phase 3 VALIANT study, among other data. Additionally, two abstracts were selected by congress organizers as Top 10 best ERA abstracts. The “Top 10” are deemed significant studies underlining the growing field of clinical research in kidney disease.

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.[1] Additionally, approximately 90% of patients who previously received a kidney transplant will experience disease recurrence.[2] The diseases are estimated to affect 5,000 people in the United States and up to 8,000 in Europe.[3]

About the VALIANT Study
The VALIANT Phase 3 study (NCT05067127) is a randomized, placebo-controlled, double-blinded, multi-center study designed to evaluate pegcetacoplan efficacy and safety in 124 patients who are 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 and post-transplant kidneys. Study participants were randomized to receive pegcetacoplan or placebo twice weekly for 26 weeks. Following this 26-week randomized 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 therapy designed to regulate excessive activation of the complement cascade, a part of the body’s immune system, which can lead to the onset and progression of many serious diseases. Pegcetacoplan is under investigation for rare diseases across hematology and nephrology. Pegcetacoplan is approved for the treatment of paroxysmal nocturnal hemoglobinuria (PNH) as EMPAVELI®/Aspaveli® in the United States, European Union, and other countries globally.

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

About 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.

About Apellis
Apellis Pharmaceuticals, Inc. is a global biopharmaceutical company that combines courageous science and compassion to develop life-changing therapies for some of the most challenging diseases patients face. We ushered in the first new class of complement medicine in 15 years and now have two approved medicines targeting C3. These include the first-ever therapy for geographic atrophy, a leading cause of blindness around the world. We believe we have only begun to unlock the potential of targeting C3 across many serious diseases. For more information, please visit http://apellis.com or follow us on X (Twitter) and LinkedIn.

Apellis Forward-Looking Statement
Apellis Forward-Looking Statement Statements in this press release about future expectations, plans and prospects, as well as any other statements regarding matters that are not historical facts, may constitute "forward-looking statements" within the meaning of The Private Securities Litigation Reform Act of 1995. These statements include, but are not limited to, statements regarding plans to submit applications for regulatory approval for the treatment of patients with C3G and IC-MPGN. The words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "will," "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including whethersystemic pegcetacoplan will receive approval for those indications from the FDA or equivalent foreign regulatory agencies when expected or at all; and any other factors discussed in the "Risk Factors" section of Apellis' Annual Report on Form 10-K with the Securities and Exchange Commission on February 28, 2025 and the risks described in other filings that Apellis may make with the Securities and Exchange Commission. Any forward-looking statements contained in this press release speak only as of the date hereof, and Apellis specifically disclaims any obligation to update any forward-looking statement, whether as a result of new information, future events or otherwise.

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3. Data on file using literature consensus.