Silence Therapeutics Completes Enrollment in SANRECO Phase 2 Study of Divesiran for Polycythemia Vera (PV)

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Rapid Completion of Phase 2 Enrollment Reflects Ongoing Momentum for Divesiran as First-in-Class siRNA for PV

Topline Results Anticipated in 3Q'26

LONDON--(BUSINESS WIRE)-- Silence Therapeutics plc (Nasdaq: SLN), a global clinical-stage company developing novel siRNA (short interfering RNA) therapies, today announced it has completed patient enrollment in the SANRECO Phase 2 study of divesiran, a first-in-class siRNA targeting TMPRSS6, for the treatment of polycythemia vera (PV). Initial topline results from the SANRECO Phase 2 study are anticipated in the third quarter of 2026.

SANRECO is a global, randomized, double-blind, placebo-controlled Phase 2 study that enrolled 48 phlebotomy-dependent PV patients. The primary endpoint is the proportion of patients receiving divesiran compared to placebo who maintain hematocrit (HCT) levels below 45% without phlebotomies between weeks 18 and 36. PV patients face a higher risk of thrombotic events, including heart attack and stroke, when HCT levels are not maintained at target levels (<45%). Secondary endpoints include safety and tolerability, pharmacokinetics, and quality of life changes.

"The rapid completion of Phase 2 enrollment highlights the growing enthusiasm for divesiran and novel treatment options to address the significant unmet need in PV," said Craig Tooman, President and Chief Executive Officer at Silence. "Despite currently approved treatment options, a serious unmet need exists for patients seeking continuous hematocrit and symptom control, improved quality of life, and more convenient dosing, which we believe divesiran has the potential to address as a first-in-class siRNA. We extend our sincerest thanks to the patients, investigators, and collaborative partners who made the achievement of this important milestone possible."

Results from the Phase 1 portion of the SANRECO study showed divesiran's potential to maintain HCT to target levels following infrequent dosing (every six weeks) without the need for phlebotomies in the target population. Based on the sustained duration of effect observed in Phase 1, the Phase 2 study includes a second, longer dosing interval of every 12 weeks.

About the SANRECO Phase 2 Study

The SANRECO Phase 2 study is a global, randomized, double-blind, placebo-controlled trial evaluating two divesiran dosing intervals (Q6W and Q12W) in 48 PV patients. The study includes a 36-week, placebo-controlled, double-blind period followed by a double-blind extension period and then an open-label extension period. The primary endpoint is the proportion of patients who achieve a response receiving divesiran compared to placebo between 18 and 36 weeks. A responder is defined as a patient with HCT remaining < 45% in the absence of phlebotomies during this time period. Secondary endpoints include safety and tolerability, pharmacokinetics and quality of life outcomes. Initial topline results are anticipated in the third quarter of 2026.

About PV

PV is a rare, myeloproliferative neoplasm – a type of blood cancer – characterized by the excessive production of red blood cells, often resulting in elevated hematocrit levels. Elevated hematocrit above 45% is associated with a four-times higher rate of death from cardiovascular or thrombotic events. PV is associated with a range of burdensome symptoms including fatigue, cognitive disturbance and pruritus. Additionally, longer term, PV can transform to myelofibrosis and Acute Myeloid Leukemia. The aim of treatment is to maintain hematocrit less than 45%, a level that is associated with a reduced incidence of thrombosis and CV-associated death. The current standard of care includes repeated phlebotomies to reduce hematocrit and/or cytoreductive agents to reduce red blood cell production. There are currently no approved therapies that specifically target red blood cells and hematocrit.

About Divesiran

Divesiran is Silence's wholly owned siRNA product candidate developed from its proprietary mRNAi GOLD™ platform designed to selectively target and "silence" production of the TMPRSS6 protein found in liver cells. TMPRSS6 is a negative regulator of hepcidin, the body's master regulator of iron metabolism. By increasing hepcidin levels, divesiran aims to redirect iron delivery away from the bone marrow, lowering red blood cell production and potentially reducing the high red blood cell count in people living with PV. Divesiran is currently in Phase 2 development for PV and has FDA Fast Track and Orphan Drug designations for PV.

About Silence Therapeutics

Silence Therapeutics is a global clinical-stage biotechnology company committed to transforming people's lives by silencing diseases through precision engineered medicines created with proprietary siRNA (short interfering RNA)

technology. Silence leverages its mRNAi GOLD™ platform to create innovative siRNAs designed to precisely target and silence disease-associated genes in the liver, which represents a substantial opportunity. Silence focuses on areas of high unmet medical need with programs in cardiovascular disease, hematology and rare diseases. For more information, please visit **https://www.silence-therapeutics.com/**.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. In some cases, you can identify forward-looking statements by terminology such as “aim,” “anticipate,” “assume,” “believe,” “contemplate,” “continue,” “could,” “design,” “due,” “estimate,” “expect,” “goal,” “intend,” “may,” “objective,” “plan,” “positioned,” “potential,” “predict,” “seek,” “should,” “target,” “will,” “would” and other similar expressions that are predictions of or indicate future events and future trends, or the negative of these terms or other comparable terminology. All statements other than statements of historical facts contained in this press release are forward-looking statements. These forward-looking statements include, but are not limited to, statements about: the potential therapeutic benefit of divesiran; continued clinical development of divesiran, including anticipated timing of initial topline and future results of the SANRECO Phase 2 trial; and the potential for divesiran to be a first-in-class siRNA for PV. Forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties that could cause actual results and events to differ materially from those anticipated, including, but not limited to, risks and uncertainties related to: the company’s history of net operating losses; the company’s ability to obtain necessary capital to fund its clinical programs; the early stages of clinical development of the company’s product candidates; the company’s ability to obtain regulatory approval of and successfully commercialize its product candidates; any undesirable side effects or other properties of the company’s product candidates; the company’s reliance on third-party suppliers and manufacturers; the outcomes of any future collaboration agreements; and the company’s ability to adequately maintain intellectual property rights for its product candidates. These and other risks are described in greater detail under the section titled “Risk Factors” contained in the company’s Annual Report on Form 10-K and Quarterly Reports on Form 10-Q and the company’s other filings with the SEC. Any forward-looking statements that the Company makes in this press release are made pursuant to the Private Securities Litigation Reform Act of 1995, as amended, and speak only as of the date of this press release. Except as required by law, the company undertakes no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise.

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