



Seelos Therapeutics Announces Additional Interim Data from Phase I Studies of Intranasal Racemic Ketamine (SLS-002)

Seelos Completed Type C Meeting with FDA to Discuss Trial Design for Study of SLS-002 for Acute Suicidal Ideation and Behavior in Patients with Major Depressive Disorder

NEW YORK, March 24, 2020 (GLOBE NEWSWIRE) -- Seelos Therapeutics, Inc. (Nasdaq: SEEL), a clinical-stage biopharmaceutical company focused on the development of therapies for central nervous system disorders and rare diseases, today announced additional interim data from its Phase I studies of Intranasal Racemic Ketamine (SLS-002). Seelos also announced that it completed its Type C meeting with the U.S. Food and Drug Administration (FDA) as scheduled to discuss the protocol design for a study of SLS-002 for Acute Suicidal Ideation and Behavior (ASIB) in patients with Major Depressive Disorder (MDD).

Interim data disclosed includes the hemodynamic (vital signs) side effect profile to address the known and expected side effects of ketamine, which are increases in blood pressure and heart rate.

Some of the key highlights of the interim vital signs adverse events (AEs) data for all 104 subjects from the Phase I studies include:

- All vital signs related AEs observed in the combined studies, SLS-002-101 and SLS-002-102, were mild and transient in nature.
- No serious adverse events (SAEs) related to vital signs were observed.
- In the open label study, SLS-002-101, only 5 out of 42 subjects (60mg dose) experienced mild and transient AEs.
- In the blinded study, SLS-002-102, only 10 out of 62 subjects experienced mild and transient AEs; the distribution of these AEs across the 6 arms (placebo, IV 0.3mg/kg and intranasal doses of 30mg, 60 mg, 75 mg and 90 mg) will be known upon unblinding the studies.

"Earlier this month, we completed our scheduled face to face Type C meeting with the FDA for input and feedback on a potential clinical study of SLS-002 for acute suicidal ideation and behavior in patients with major depressive disorder," said Raj Mehra, Ph.D., Chairman and CEO of Seelos. "We continue to be extremely pleased with the side effect profile of SLS-002 to date and will continue to work closely with the agency on the design of the protocol for the next study."

Additional data from the Phase I studies is expected to be released early in the second quarter of 2020 once all dose cohorts are unblinded and evaluated.

Forward-Looking Statements

Statements made in this press release, which are not historical in nature, constitute forward-looking statements for purposes of the safe harbor provided by the Private Securities Litigation Reform Act of 1995. These statements include, among others, those regarding the interim results of the Phase I studies of SLS-002, the side effect profile of SLS-002, the vital signs adverse events data from the Phase I studies of SLS-002, the expected timing for releasing additional data from the Phase I studies and Seelos' proposed Phase III trial design for ASIB in patients with MDD. These statements are based on Seelos' current expectations and beliefs and are subject to a number of factors and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. Risks associated with Seelos' business include, but are not limited to, the risk of not successfully executing its clinical studies and not gaining marketing approvals for its product candidates, the risks associated with the implementation of a new business strategy, the risks related to raising capital to fund its development plans and ongoing operations, risks related to Seelos' current stock price, risks related to COVID-19, as well as other factors expressed in Seelos' periodic filings with the U.S. Securities and Exchange Commission, including its Annual Report on Form 10-K and Quarterly Reports on Form 10-Q. Although we believe that the expectations reflected in our forward-looking statements are reasonable, we do not know whether our expectations will prove correct. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof, even if subsequently made available by us on our website or otherwise. We do not undertake any obligation to update, amend or clarify these forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required under applicable securities laws.

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