Seelos Therapeutics Doses First Patients in an Ethnobridging Study with SLS-002 (Intranasal Racemic Ketamine)

-Seelos is conducting a Phase I ethnobridging study in healthy Japanese and non-Asian subjects to evaluate the safety and pharmacokinetic profiles of SLS-002.

NEW YORK, Feb. 6, 2023 /PRNewswire/ -- 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 that it has dosed the first patients in an ethnobridging study in healthy adult Japanese and non-Asian subjects to compare the safety and pharmacokinetic profiles of SLS-002 (intranasal racemic ketamine). Seelos consulted and received endorsement from the Pharmaceuticals and Medical Devices Agency (PMDA) in Japan and from the U.S. Food and Drug Administration (FDA) to conduct this Phase I ethnobridging study.

"This ethnobridging study is an important first step as we begin evaluating the potential for SLS-002 in patients globally," said Raj Mehra, Ph.D., Chairman and CEO of Seelos. "Our market research suggests a high unmet global need for a therapy with both antidepressant and anti-suicidal effects."

Study SLS-002-103 will measure elements such as dosage and administration, sample size, inclusion and exclusion criteria, endpoints, and blood sampling. Seelos expects that data from this study will help inform inclusion of Japanese subjects in the design of a future global trial in patients with major depressive disorder (MDD) at imminent risk of suicide.

If you or a loved one are having thoughts of suicide, please seek immediate medical help, go to your nearest emergency room, call the **Suicide and Crisis Lifeline** at 988 or 1-800-273-8255 (TALK).

About SLS-002

SLS-002 is intranasal racemic ketamine with two investigational new drug applications for the treatment of Acute Suicidal Ideation and Behavior in Major Depressive Disorder and in Post-Traumatic Stress Disorder. SLS-002 was originally derived from a Javelin Pharmaceuticals, Inc./Hospira, Inc. program with 16 clinical studies involving approximately 500 subjects. Seelos looks to address an unmet need for a therapy to treat suicidality in the U.S. with SLS-002. Traditionally, anti-depressants have been used in this setting but many of the existing treatments are known to contribute to an increased risk of suicidal thoughts in some circumstances, and if they are effective, it often takes weeks for the full therapeutic effect to be manifested. The clinical development program for SLS-002 includes two parallel healthy volunteer studies (Phase I), followed by pivotal registration studies after meeting with the FDA. Based on information gathered from the databases of the Agency for Healthcare Research and Quality, there were more than 1,000,000 visits to emergency rooms for suicide attempts in 2019 in the U.S. alone. Experimental studies suggest ketamine has the potential to be a rapid, effective treatment for refractory depression and suicidality.

About Seelos Therapeutics

Seelos Therapeutics, Inc. is a clinical-stage biopharmaceutical company focused on the development and advancement of novel therapeutics to address unmet medical needs for the benefit of patients with central nervous system (CNS) disorders and other rare diseases. The Company's robust portfolio includes several late-stage clinical assets targeting indications including Acute Suicidal Ideation and Behavior (ASIB) in Major Depressive Disorder (MDD), amyotrophic lateral sclerosis (ALS), spinocerebellar ataxia (SCA), Sanfilippo syndrome, Parkinson's disease, other psychiatric and movement disorders plus orphan diseases.

For more information, please visit our website: **https://seelostherapeutics.com**, the content of which is not incorporated herein by reference.

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 Seelos' Phase I ethnobridging study of SLS-002, including SLS-002's prospects and potential insights from the Phase I ethnobridging study, as well as statements regarding the anticipated enrollment and timing of the study and the potential for the data from the study to help inform inclusion of Japanese subjects in the design of a future global trial in patients with MDD. These statements are based on Seelos' current expectations and beliefs and are subject to a number of risks and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. Risks associated with Seelos' business and plans described herein include, but are not limited to, the risk of not successfully executing its preclinical and clinical studies, and not gaining marketing approvals for its product candidates, the risk that prior clinical results may not be replicated in future studies and trials, the risks that clinical study results may not meet any or all endpoints of a clinical study and that any data generated from such studies may not support a regulatory submission or approval, 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 the global impact of COVID-19, as well as other factors expressed in Seelos' periodic filings with the U.S. Securities and Exchange Commission, including its most recent 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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