Seelos Therapeutics Doses the First Amyotrophic Lateral Sclerosis (ALS) Patient with SLS-005 in an Expanded Access Program

- The Expanded Access Program is funded by a grant from the National Institute of Neurological Disorders and Stroke (NINDS) under the Accelerating Access to Critical Therapies for ALS (ACT for ALS) for ALS patients who do not qualify for existing clinical trials

NEW YORK, April 4, 2023 /PRNewswire/ -- Seelos Therapeutics, Inc. (Nasdaq: SEEL) ("Seelos"), a clinical-stage biopharmaceutical company focused on the development of therapies for central nervous system disorders and rare diseases, today announced it has dosed the first patient in an Expanded Access Program (EAP) for patients with ALS who do not qualify for existing clinical trials and that the EAP will be fully funded by a grant from the NINDS under the ACT for ALS.

Under this EAP, Seelos plans to initially enroll 70 patients in a 24-week, open-label study to evaluate SLS-005 in persons with ALS in parallel to its ongoing, fully enrolled, randomized double-blind placebo-controlled Phase II/III study on the HEALEY ALS Platform.

"Initiating this EAP is an important event for Seelos and for patients in need of therapy who cannot participate in existing clinical trials. We are grateful for the support from the ALS community, the Healey platform team and for the funding from NINDS," said Raj Mehra Ph.D., Chairman and CEO of Seelos.

If you are a person with ALS (PALS) or caregiver of someone with ALS (CALS) and would like more information, please visit: **https://seelostherapeutics.com/patients-and-caregivers/**

About the Accelerating Access to Critical Therapies for ALS Act (ACT for ALS)

The ACT for ALS, Public Law 117-79, among other things, requires the Department of Health and Human Services (HHS), through the Food and Drug Administration (FDA) and the National Institutes of Health (NIH), to implement a Public-Private Partnership for Rare Neurodegenerative Diseases through cooperative agreements or contracts to advance the understanding of neurodegenerative diseases and foster development of treatments for ALS and other rare neurodegenerative diseases. It requires the FDA to publish and implement a 5-year action plan to foster drug development and facilitate access to investigational drugs for ALS and other rare neurodegenerative diseases. Finally, it requires that the FDA award grants or contracts to public and private entities to cover costs of research on, and development of interventions intended to prevent, diagnose, mitigate, treat, or cure ALS and other rare neurodegenerative diseases in adults and children.

More information on ACT for ALS is available **here**.

More information about NINDS is available **here**.

About SLS-005 (trehalose injection, 90.5 mg/mL for intravenous infusion)

SLS-005 is a low molecular weight disaccharide (0.342 kDa) that crosses the blood brain barrier and is thought to stabilize proteins and activate autophagy through the activation of Transcription Factor EB (TFEB), a key factor in lysosomal and autophagy gene expression. Activation of TFEB is an emerging therapeutic target for a number of diseases with pathologic accumulation of storage material. In animal models of several diseases associated with abnormal cellular protein aggregation or storage of pathologic material, SLS-005 has been shown to reduce aggregation of misfolded proteins and reduce accumulation of pathologic material. SLS-005 is an investigational treatment and is not currently approved by any health authority for medicinal use.

About Amyotrophic Lateral Sclerosis (ALS)

According to the National Institute of Neurological Disorders and Stroke, amyotrophic lateral sclerosis (ALS) is a group of rare neurological diseases that mainly involve the nerve cells (neurons) responsible for controlling voluntary muscle movement. In ALS, both the upper motor neurons and the lower motor neurons degenerate or die and stop sending messages to the muscles. Unable to function, the muscles gradually weaken, start to twitch (called fasciculations), and waste away (called atrophy). Eventually, the brain loses its ability to initiate and control voluntary movements. The disease is progressive, meaning the symptoms get worse over time. The majority of ALS cases (90 percent or more) are considered sporadic. This means the disease seems to occur at random with no clearly associated risk factors and no family history of the disease. Although family members of people with sporadic ALS are at an increased risk for the disease, the overall risk is very low, and most will not develop ALS.

Most people with ALS eventually die from respiratory failure, usually within 3 to 5 years from when the symptoms first appear. However, about 10 percent of people with ALS survive for 10 or more years. Currently, there is no cure for ALS and no effective treatment to halt or reverse, the progression of the disease.

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 the number of patients to be enrolled in the EAP, the expected duration of the EAP, as well as statements regarding Seelos' study on the HEALEY ALS platform and statements regarding SLS-005's prospects and potential insights from the EAP. 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 Seelos' 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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