



## Seelos Therapeutics Receives Positive EMA Opinion on Orphan Drug Designation for SLS-005 (Trehalose) in Amyotrophic Lateral Sclerosis (ALS)

NEW YORK, April 20, 2021 /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 it has received a positive opinion on European Orphan Drug Designation for SLS-005 in amyotrophic lateral sclerosis (ALS) from the European Medicines Agency (EMA) Committee for Orphan Medicinal Products (COMP).



The positive opinion issued by COMP will be sent to the European Commission, which is expected to grant the orphan designation within 30 days. Under orphan designation in the European Union (EU), Seelos stands to benefit from several incentives such as protocol assistance, reduced regulatory fees and market exclusivity. European guidelines for Orphan Drug Designation are for diseases affecting not more than five in 10,000 people in the EU.

In November, SLS-005 was granted Orphan Drug Designation from the U.S. Food and Drug Administration (FDA) for ALS. SLS-005 was previously granted Orphan Drug Designation from the FDA and EMA for Spinocerebellar Ataxia Type 3 (SCA3), Sanfilippo syndrome and Oculopharyngeal Muscular Dystrophy (OPMD). SLS-005 has also been granted Fast Track designation from the FDA for OPMD.

### 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 receipt of Orphan Drug Designation for the EU for SLS-005 in amyotrophic lateral sclerosis from the European Commission, the expected timing for receiving Orphan Drug Designation from the European Commission and the expected incentives associated with receiving Orphan Drug Designation for SLS-005. 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 that the European Commission does not grant Orphan Drug Designation for the EU for SLS-005 in amyotrophic lateral sclerosis, the risk of Seelos not successfully executing its preclinical and 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 Seelos' 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 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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