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Cytokinetics Announces Start of Open-Label Extension Study for Patients Completing COURAGE-ALS

Managed Access Program for People Who Have Completed Prior Cytokinetics ALS Trials to Begin in 2H 2022

Cytokinetics announced the start of COURAGE-ALS OLE (**C**linical **O**utcomes **U**sing ***R**eldesemtiv* on **A**LSFRS-R in a **G**lobal **E**valuation in **ALS** **O**pen **L**abel **E**xtension), an open-label extension clinical study designed to assess the long-term safety and tolerability of *reldesemtiv* in people with amyotrophic lateral sclerosis (ALS). Patients will be eligible for COURAGE-ALS OLE after completing their participation in COURAGE-ALS, the Phase 3 clinical trial of *reldesemtiv*, a next-generation fast skeletal muscle troponin activator (FSTA) for the potential treatment of ALS.

"We are pleased to provide continued access to *reldesemtiv* through the open-label extension study of COURAGE-ALS as is aligned with our commitment to people with ALS. This open-label extension will also allow us to gather longer-term data related to the effect of treatment with *reldesemtiv* on disease progression in ALS," said Fady I. Malik, M.D., Ph.D., Cytokinetics' Executive Vice President of Research & Development. "Additionally, we look forward to opening a Managed Access Program for *reldesemtiv* later this year for participants who completed our prior ALS clinical trials. ALS is a devastating, fatal disease with few approved therapies, and we recognize the urgency to provide access to people who have committed to our extensive clinical research while we also advance *reldesemtiv* in our ongoing Phase 3 clinical trial"

COURAGE-ALS OLE: Clinical Study Design

COURAGE-ALS OLE is an open-label extension clinical study of *reldesemtiv* in people with ALS who have completed participation in COURAGE-ALS. Following enrollment in COURAGE-ALS OLE, participants will continue to receive 300 mg of *reldesemtiv* dosed orally twice daily for 48 weeks after which they may transition into the Managed Access Program. The primary endpoint is the incidence of adverse events. Secondary endpoints include the time to the first occurrence of respiratory insufficiency or death, time to the first hospitalization, combined assessment of change in ALSFRS-R total score, time to onset of respiratory insufficiency, and survival time, changes in ALSFRS-R total score, and the slope of changes in ALSFRS-R total score. Additional information on COURAGE-ALS OLE can be found at clinicaltrials.gov.

Source: **Cytokinetics**