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Corcept Announces Results From Phase 2 Study of Dazucorilant in Patients With Amyotrophic Lateral Sclerosis (ALS)

Corcept Therapeutics, a commercial-stage company engaged in the discovery and development of medications to treat severe endocrinologic, oncologic, metabolic, and neurologic disorders by modulating the effects of the hormone cortisol, announced results from the **DAZALS study**, a randomized, double-blind, placebo-controlled, Phase 2 trial evaluating two doses (150 mg and 300 mg) of its proprietary selective cortisol modulator dazucorilant in patients with ALS. Upon completion of the trial, patients were eligible to enter an open-label, long-term extension study, in which they received 300 mg of dazucorilant.

DAZALS did not meet its primary endpoint, which was the change from baseline in the ALS Functional Rating Scale-Revised (ALSFRS-R) in patients who received dazucorilant compared to those who received placebo. Patients who received dazucorilant experienced substantially more gastrointestinal upset at the onset of treatment than those who received placebo. During the 24-week study, no deaths (0/83) were observed in the 300 mg arm, compared to 5 deaths (5/82) in the placebo group (p-value: 0.02). The open-label, long-term extension study will continue and overall survival will be assessed in March 2025 after all patients have had one year pass since the onset of treatment. Dazucorilant has been granted Fast Track Designation by the U.S. Food and Drug Administration.

Complete results from the DAZALS study will be presented at a medical conference next year.

About the DAZALS Study

DAZALS enrolled 249 patients, randomized 1:1:1 to receive either 150 mg of dazucorilant, 300 mg of dazucorilant or placebo daily for 24 weeks. The study's primary endpoint was to slow the decline in motor skills and other functional criteria,

compared to placebo, as measured by the ALSFRS-R. Key secondary endpoints include overall survival and quality of life. Patients were provided the opportunity to receive 300mg of dazucorilant for 132 weeks in the open-label, long-term extension of the DAZALS study. DAZALS is being conducted at sites in Europe, the United States and Canada.

About Dazucorilant

Dazucorilant is a selective cortisol modulator that binds to the glucocorticoid receptor but does not bind to the body's other hormone receptors. Corcept is studying it as a potential treatment for ALS and other neurologic disorders. Dazucorilant is proprietary to Corcept and is protected by composition of matter, method of use and other patents.

Source: **Press release Corcept Therapeutics**