

Corcept Therapeutics Initiates Second Phase 2 Trial of Miricorilant to Treat Weight Gain Caused by Antipsychotic Medication

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MENLO PARK, Calif., Sept. 10, 2020 (GLOBE NEWSWIRE) -- Corcept Therapeutics Incorporated (NASDAQ: CORT), a commercial-stage company engaged in the discovery and development of drugs to treat severe metabolic, oncologic and psychiatric disorders by modulating the effects of cortisol, today announced enrollment of its first patient in GRATITUDE II, a randomized, double-blind, placebo-controlled, Phase 2 trial of miricorilant in obese patients with schizophrenia and long-standing antipsychotic-induced weight gain (APIWG).

GRATITUDE II has a planned enrollment of 150 patients, who will continue to receive their established dose of antipsychotic medication, plus either 600 milligrams of miricorilant, 900 milligrams of miricorilant or placebo, for 26 weeks. The primary endpoint is reduction in bodyweight. GRATITUDE II will be conducted at 35 centers in the United States.

GRATITUDE I, Corcept's first Phase 2 trial of miricorilant in APIWG, continues to enroll patients with schizophrenia and recent weight gain. Patients in GRATITUDE I receive, in addition to their established antipsychotic regimen, either 600 milligrams of miricorilant or placebo for 12 weeks. The primary endpoint is change in bodyweight.

"Substantial, sustained weight gain and associated metabolic co-morbidities shorten the lives of many of the millions of patients who take antipsychotic medications and significantly reduce quality of life for many more," said Andreas Grauer, MD, Corcept's Chief Medical Officer. "Miricorilant has demonstrated promise as a potential treatment for this disorder. In our double-blind, placebo-controlled, Phase 1b trial, after just two weeks of treatment, healthy subjects given miricorilant in addition to olanzapine gained significantly less weight than subjects who received olanzapine plus placebo. Patients receiving miricorilant also experienced smaller increases in the enzymes AST and ALT, which suggests miricorilant may help protect the liver. We hope to confirm and extend our Phase 1b results in GRATITUDE II, which is using an improved formulation of miricorilant and a longer treatment duration."

About Corcept Therapeutics

Corcept is a commercial-stage company engaged in the discovery and development of drugs to treat severe metabolic, oncologic and psychiatric disorders by modulating the effects of the hormone cortisol. Korlym[®] was the first drug approved by the U.S. Food and Drug Administration for patients with Cushing's syndrome. Corcept has discovered a large portfolio of proprietary compounds that selectively modulate the effects of cortisol. The company owns extensive United States and foreign intellectual property covering the composition of its selective cortisol modulators and the use of cortisol modulators to treat a variety of serious disorders.

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¹ For data from our studies in animal models of APIWG, see our <u>2020 American Psychiatry Association (APA)</u> poster at the Research & Pipeline / Publications tab of our website.



Source: Corcept Therapeutics Incorporated