



Corcept Therapeutics Completes Enrollment in Phase 2 GRATITUDE Study of Miricorilant in Patients with Antipsychotic-Induced Weight Gain

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Data to be Available in Fourth Quarter 2022

MENLO PARK, Calif., April 04, 2022 (GLOBE NEWSWIRE) -- Corcept Therapeutics Incorporated (NASDAQ: CORT), a commercial-stage company engaged in the discovery and development of drugs to treat severe endocrine, metabolic, oncologic and neurological disorders by modulating the effects of the hormone cortisol, today announced completion of enrollment in GRATITUDE – the company's double-blind, placebo-controlled trial of its proprietary, selective cortisol modulator miricorilant as a potential treatment for patients with weight gain caused by antipsychotic medication use. Data will be available in the fourth quarter of this year.

GRATITUDE is evaluating the efficacy, pharmacokinetics and safety of miricorilant among adult patients with schizophrenia or bipolar disorder and recent antipsychotic-induced weight gain. Patients were randomized 1:1 to receive either 600 milligrams of miricorilant or placebo each day, in addition to their established dose of antipsychotic medication, for 12 weeks.

Earlier this year, Corcept completed enrollment in a second study, GRATITUDE II, which is evaluating miricorilant as a treatment for long-standing antipsychotic-induced weight gain. In GRATITUDE II, patients with schizophrenia were randomized 1:1:1 to receive, in addition to their established dose of antipsychotic medication, either 600 milligrams or 900 milligrams of miricorilant or placebo each day for 26 weeks. Data from this study also will be available in the fourth quarter.

The primary endpoint in both GRATITUDE and GRATITUDE II is reduction in body weight compared to patients receiving placebo. Other important measures of metabolic activity will also be examined.

"Unfortunately, many of the most effective antipsychotics are also associated with significant weight gain, which poses an additional risk to the health of patients who are already suffering from schizophrenia and related disorders," commented Dr. Joshua Kantrowitz, who is leading the trial at New York State Psychiatric Institute and Columbia University Irving Medical Center. "The studies of miricorilant underway will provide important data to determine whether the weight gain and related adverse impact on cardiovascular and overall health associated with many antipsychotic medications can be mitigated."

Antipsychotic-Induced Weight Gain

In the United States, six million people take antipsychotic medications such as olanzapine and risperidone to treat life threatening psychiatric disorders such as schizophrenia, bipolar disorder and depression. While these drugs are very effective, rapid and sustained weight gain associated with their use can lead to cardiovascular and metabolic disease.

Corcept's clinical program seeks to build on positive data from earlier studies of cortisol modulation in healthy subjects. In 2020, Corcept completed a double-blind, placebo-controlled trial in which 96 healthy subjects received olanzapine and either 600 or 900 milligrams of miricorilant or placebo for 14 days. Subjects who received miricorilant gained significantly less weight than those who received placebo. These results were published in the Journal of Clinical Psychopharmacology¹.

About Corcept Therapeutics

Corcept has discovered a large portfolio of proprietary compounds that selectively modulate the effects of cortisol and owns extensive United States and foreign intellectual property covering both their composition and their use to treat a variety of serious disorders. The company is conducting clinical trials of its leading cortisol modulators as potential treatments for patients with Cushing's syndrome, ovarian, adrenal and prostate cancer, weight gain caused by the use of antipsychotic medications and liver disease. Corcept's drug Korlym[®] was the first medication approved by the U.S. Food and Drug Administration for the treatment of patients with Cushing's syndrome.

Forward Looking Statements

Statements in this press release, other than statements of historical fact, are forward-looking statements based on our current plans and expectations that are subject to risks and uncertainties that might cause our actual results to differ materially from those such statements express or imply. These risks and uncertainties include, but are not limited to, our ability to operate our business, conduct our clinical trials and achieve our other goals during the COVID-19 pandemic; risks related to the development of miricorilant and other product candidates, including their clinical attributes, the availability of data in the timeframe anticipated, regulatory approvals, mandates, oversight and other requirements; and the scope and protective power of our intellectual property. These and other risks are set forth in our SEC filings, which are available at our website and the SEC's website. We disclaim any intention or duty to update forward-looking statements made in this press release.

¹ H. J. Hunt et al. J Clin Psychopharmacol. 2021 Nov-Dec 01;41(6):632-637. <https://pubmed.ncbi.nlm.nih.gov/34369902/>

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