Corcept Therapeutics Announces First Patient Dosed in Phase 3 Trial of Relacorilant to Treat Patients with Cushing's Syndrome

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MENLO PARK, Calif., Nov. 19, 2018 (GLOBE NEWSWIRE) -- Corcept Therapeutics Incorporated (NASDAQ: CORT), a company engaged in the discovery, development and commercialization of drugs to treat severe metabolic, oncologic and psychiatric disorders by modulating the effects of the stress hormone cortisol, today announced that it dosed the first patient in the Phase 3 trial of relacorilant to treat patients with Cushing's syndrome.

"We are excited to enroll the first patient in relacorilant's Phase 3 trial," said Joseph K. Belanoff, MD, Corcept's Chief Executive Officer. "Patients in Phase 2 experienced significant clinical benefit without Korlym's serious off-target effects – endometrial thickening, vaginal bleeding and hypokalemia. Confirming these results in Phase 3 would constitute a major medical advance."

"I also want to thank our development team, and especially our Chief Medical Officer, Dr. Robert S. Fishman, for their tireless efforts in advancing relacorilant and our other product candidates," said Dr. Belanoff. "Our clinical programs are poised to make significant progress in a wide variety of serious disorders – Cushing's syndrome, pancreatic, ovarian and prostate cancer, non-alcoholic steato-hepatitis (NASH) and antipsychotic-induced weight gain. Patients with these serious disorders have few good options. If we are successful in developing treatments for them, it will be in no small part because of Bob's insight, and hard work." As announced earlier today, Dr. Fishman, will be stepping down from his position as Corcept's Chief Medical Officer, effective January 31st, 2019.

The Phase 3 trial (entitled "GRACE") is expected to enroll 130 patients with Cushing's syndrome at sites in the United States, Canada and Europe. The trial has a two-phase design. In the initial, open-label portion, all patients will receive relacorilant for 22 weeks, with doses starting at 100 mg per day, then increasing in 100 mg increments, as clinically indicated, to a maximum of 400 mg per day. After 22 weeks, patients who exhibit pre-specified improvements in glucose tolerance or hypertension – two of Cushing's syndrome's most common and pernicious symptoms – will enter a double-blind, placebo-controlled, withdrawal phase lasting 12 weeks. Half of the patients entering this phase will continue to receive relacorilant. The rest will receive placebo. The rate and degree of relapse in patients receiving placebo will be measured against the same parameters in patients continuing relacorilant.

The FDA has designated relacorilant an orphan drug for the treatment of patients with Cushing's syndrome. Corcept has been issued patents covering relacorilant's composition of matter and method of use that expire in 2033.

Cushing's Syndrome

Hypercortisolism, often referred to as Cushing's syndrome, is caused by excessive activity of the stress hormone cortisol. Endogenous Cushing's syndrome is an orphan disease that most often affects adults aged 20-50. In the United States, an estimated 20,000 patients have Cushing's syndrome, with about 3,000 new patients being diagnosed each year. Symptoms vary, but most people experience one or more of the following manifestations: high blood sugar, diabetes, high blood pressure, upper-body obesity, rounded face, increased fat around the neck, thinning arms and legs, severe fatigue and weak muscles. Irritability, anxiety, cognitive disturbances and depression are also common. Cushing's syndrome can affect every organ system in the body and can be lethal if not treated effectively.

About Corcept Therapeutics Incorporated

Corcept is a pharmaceutical company engaged in the discovery, development and commercialization of drugs that treat severe metabolic, oncologic and psychiatric disorders by modulating the effects of the stress hormone cortisol. Korlym® is the company's first FDA-approved medication. We have discovered a large portfolio of proprietary compounds that selectively modulate the effects of cortisol but not progesterone. We own extensive United States and foreign intellectual property covering the composition of our selective cortisol modulators and the use of cortisol modulators, including Korlym, to treat a wide variety of serious disorders.

Forward-Looking Statements

Statements in this press release, other than statements of historical fact, are forward-looking statements for purposes of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, are based on our current plans and expectations and are subject to risks and uncertainties that might cause 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 generate sufficient revenue to fund our commercial operations and development programs; the protections afforded by relacorilant's orphan drug designation and our intellectual property; and risks related to the development of relacorilant, including regulatory approvals, mandates, oversight and other requirements. These and other risks are set forth in our Securities and Exchange Commission ("SEC") filings, which are available at our website and the SEC's website. In this press release, forward looking statements include those concerning the clinical development of relacorilant, its safety and efficacy profile, its potential to benefit patients with Cushing's syndrome and our ability to make it available to those patients. We disclaim any intention or duty to update forward-looking statements made in this press release.

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