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## **Corcept Therapeutics Incorporated Announces FDA Approval of Korlym(TM) (Mifepristone): First and Only Approved Medication for Cushing's Syndrome Patients**

MENLO PARK, CA -- (Marketwire - February 17, 2012) - Corcept Therapeutics Incorporated (NASDAQ: CORT) announced today that the U.S. Food and Drug Administration (FDA) has approved Korlym™ (mifepristone 300 mg tablets) as a once-daily oral medicine to control hyperglycemia secondary to hypercortisolism in adult patients with endogenous Cushing's syndrome who have diabetes mellitus type 2 or glucose intolerance and have failed surgery or are not candidates for surgery.

"We appreciate the FDA's diligent attention to our NDA and its grant of approval on the PDUFA date," said Joseph K. Belanoff, M.D., the company's Chief Executive Officer. "We plan to make Korlym available to patients by May 1 through a distribution system designed to support both patients and prescribers."

Corcept will be the sole marketer of Korlym. "A relatively small number of endocrinologists regularly treat patients with Cushing's syndrome," added Dr. Belanoff. "These doctors can be reached without a large sales and marketing infrastructure." The company has begun hiring Medical Science Liaisons to inform practitioners about the drug, which will be dispensed by the leading specialty pharmacy company CuraScript SP, a subsidiary of Express Scripts.

"Korlym is a significant advance in the treatment of patients suffering from the debilitating symptoms of Cushing's syndrome," said Robert L. Roe, M.D., Corcept's President. "For the first time, these patients have access to an approved therapy when surgery has failed or is not an option."

Korlym clinical trial investigator Amir Hamrahan, M.D., Department of Endocrinology, Diabetes and Metabolism at the Cleveland Clinic said, "There are not many effective treatment options for patients with Cushing's syndrome. Although surgery is standard first line treatment for the disease, it is not always successful and not all patients are candidates. As part of the clinical trial, I have used Korlym successfully and my patients continue to do well on the medicine. I'm excited to be able to continue using Korlym in these patients and others who need it. This medicine's approval gives me a much needed tool to better treat patients."

Dr. Hamrahan's comments were seconded by Maureen V., a patient in Corcept's Phase 3 clinical trial: "I had pituitary surgery to treat my Cushing's syndrome. Unfortunately, my surgery wasn't successful. I was lucky to get into the study and get Korlym treatment. I have been taking the medicine successfully for over a year, and I am extremely happy that it was approved by the FDA. Now I know I'll be able to keep taking it. It has made a big difference in my life."

### **Clinical Trial Results Supporting FDA Approval**

The clinical data supporting the FDA approval of Korlym resulted from an uncontrolled, open-label, multi-center, 24-week phase III study of 50 patients who had endogenous Cushing's syndrome and were either not eligible for or had relapsed from surgery and were either glucose intolerant (29 patients) or had hypertension (21 patients). Within the glucose intolerant group, 60 percent of patients had a greater than 25 percent reduction from baseline in the area under the curve in the oral glucose tolerance test. In this group, mean hemoglobin A1C (HbA1C) was reduced from 7.4 percent to 6.3 percent. All 14 patients with above-normal HbA1C levels at baseline experienced reductions. Eight of

these 14 normalized their HbA1C. Antidiabetic medications were reduced in seven of the 15 patients with diabetes mellitus type 2 and remained constant in the others.

Patients who responded to therapy were allowed enrollment in an extension trial. Eighty-eight percent of the patients who completed the trial chose to do so.

A peer-reviewed analysis of the study results will soon be published in a leading journal.

Patients in the study started Korlym treatment on a dose of 300 mg administered once daily. Their dose was then titrated to maximum clinical effect. As indicated in the medicine's label, physicians prescribing Korlym may determine the appropriate dose for each patient by assessing tolerability and degree of improvement in Cushing's syndrome manifestations. In the first six weeks, these manifestations may include changes in glucose control, anti-diabetic medication requirements, insulin levels and psychiatric symptoms. After two months, assessment may also be based on improvements in cushingoid appearance, acne, hirsutism, striae, decreased body weight, along with further changes in glucose control.

#### **About Korlym™ (mifepristone 300 mg tablets)**

Korlym is a once-daily oral medication that blocks the glucocorticoid receptor type II (GR-II) to which cortisol normally binds. By blocking this receptor, Korlym inhibits the effects of excess cortisol in Cushing's syndrome patients.

The FDA has designated Korlym as an Orphan Drug for treatment of the clinical manifestations of endogenous Cushing's syndrome. Orphan Drug designation is a special status designed to encourage the development of medicines for rare diseases and conditions. Because Korlym is an Orphan Drug, Corcept will have marketing exclusivity consistent with the FDA's designation until February 2019.

#### **About Cushing's Syndrome**

Endogenous Cushing's syndrome is a rare and life-threatening endocrine disorder that results from long-term exposure to excess levels of the hormone cortisol. This excess is caused by tumors that usually occur in the pituitary or adrenal glands that over-produce, or prompt the over-production of, cortisol.

Although cortisol at normal levels is essential to health, in excess it causes a variety of problems, including hyperglycemia, upper body obesity, a rounded face, stretch marks on the skin, an accumulation of fat on the back, thin and easily bruised skin, muscle weakness, bone weakness, persistent infections, high blood pressure, fatigue, irritability, anxiety, psychosis and depression. Women may have menstrual irregularities and facial hair growth, while men may have decreased fertility or erectile dysfunction. More than 70 percent of Cushing's syndrome patients suffer from glucose intolerance or diabetes.

The treatment of an endogenous Cushing's syndrome patient depends on the cause. The first-line approach is surgery to remove the tumor. If surgery is not successful or is not an option, radiation may be used, but that therapy can take up to ten years to achieve full effect. Surgery and radiation are successful in only approximately one-half of all cases.

If left untreated, Cushing's syndrome has a five-year mortality rate of 50 percent.

An orphan disease, Cushing's syndrome occurs in about 20,000 people in the United States, mostly women between the ages of 20 and 50.

### Conference Call Information

Concept will hold a conference call on Tuesday, February 21, 2012 at 9:00 a.m. Eastern Time (6:00 a.m. Pacific Time) to discuss this announcement. To participate in the live call please dial 1-800-264-7882 from the United States or +1-847-413-3708 internationally. The pass code is 31838602. Please dial in approximately 10 minutes before the start of the call.

A replay of the conference call will be available through March 6, 2012 at 1-888-843-7419 from the United States and +1-630-652-3042 internationally. The pass code is 31838602.

### IMPORTANT SAFETY INFORMATION

#### WARNING: TERMINATION OF PREGNANCY

See full prescribing information for complete boxed warning.

Mifepristone has potent antiprogesterone effects and will result in the termination of pregnancy. Pregnancy must therefore be excluded before the initiation of treatment with Korlym, or if treatment is interrupted for more than 14 days in females of reproductive potential.

#### Contraindications

- Pregnancy
- Use of simvastatin or lovastatin and CYP 3A substrates with narrow therapeutic range
- Concurrent long-term corticosteroid use
- Women with history of unexplained vaginal bleeding
- Women with endometrial hyperplasia with atypia or endometrial carcinoma

#### Warnings and Precautions

- Adrenal insufficiency: Patients should be closely monitored for signs and symptoms of adrenal insufficiency.
- Hypokalemia: Hypokalemia should be corrected prior to treatment and monitored for during treatment.
- Vaginal bleeding and endometrial changes: Women may experience endometrial thickening or unexpected vaginal bleeding. Use with caution if patient also has a hemorrhagic disorder or is on anti-coagulant therapy.
- QT interval prolongation: Avoid use with QT interval-prolonging drugs, or in patients with potassium channel variants resulting in a long QT interval.
- Use of Strong CYP3A Inhibitors: Concomitant use can increase mifepristone plasma levels significantly. Use only when necessary and limit mifepristone dose to 300 mg.

#### Adverse Reactions

Most common adverse reactions in Cushing's syndrome ( $\geq 20\%$ ): nausea, fatigue, headache, decreased blood potassium, arthralgia, vomiting, peripheral edema, hypertension, dizziness, decreased appetite, endometrial hypertrophy.

**To report suspected adverse reactions, contact Concept Therapeutics at 1-855-844-3270 or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).**

#### Drug Interactions

- Drugs metabolized by CYP3A: Administer drugs that are metabolized by CYP3A at the lowest dose when used with Korlym.
- CYP3A inhibitors: Caution should be used when Korlym is used with strong CYP3A inhibitors. Limit mifepristone dose to 300 mg per day when used with strong CYP3A inhibitors.
- CYP3A inducers: Do not use Korlym with CYP3A inducers.
- Drugs metabolized by CYP2C8/2C9: Use the lowest dose of CYP2C8/2C9 substrates when used with Korlym.
- Drugs metabolized by CYP2B6: Use of Korlym should be done with caution with bupropion and efavirenz.
- Hormonal contraceptives: Do not use with Korlym.

### **Use in Specific Populations**

- Nursing mothers: Discontinue drug or discontinue nursing.

**Please see the accompanying full Prescribing Information including boxed warning at [www.corcept.com/prescribinginfo.pdf](http://www.corcept.com/prescribinginfo.pdf)**

**Please see the accompanying Medication Guide at [www.corcept.com/medicationguide.pdf](http://www.corcept.com/medicationguide.pdf)**

### **About Corcept Therapeutics Incorporated**

Corcept is a pharmaceutical company engaged in the discovery, development and commercialization of drugs for the treatment of severe metabolic and psychiatric disorders. Korlym, a first generation GR-II antagonist, is the company's first FDA-approved medication. The company has a portfolio of new selective GR-II antagonists that block the effects of cortisol but not progesterone. Corcept also owns an extensive intellectual property portfolio covering the use of GR-II antagonists, including mifepristone, in the treatment of a wide variety of psychiatric and metabolic disorders. The company also holds composition of matter patents for its selective GR-II antagonists.

Statements made in this news release, other than statements of historical fact, are forward-looking statements. Forward-looking statements are subject to a number of known and unknown risks and uncertainties that might cause actual results to differ materially from those expressed or implied by such statements. For example, there can be no assurances that clinical results will be predictive of real-world use, or regarding the pace of Korlym's acceptance by physicians and patients, the reimbursement decisions of government or private insurance payers, the effects of rapid technological change and competition, the protections afforded by Korlym's Orphan Drug Designation or by Corcept's other intellectual property rights, and the cost, pace and success of Corcept's other product development efforts. These and other risks are set forth in the Company's SEC filings, all of which are available from our website ([www.corcept.com](http://www.corcept.com)) or from the SEC's website ([www.sec.gov](http://www.sec.gov)). We disclaim any intention or duty to update any forward-looking statement made in this news release.

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