



Corcept Therapeutics Settles Patent Litigation with Hikma Pharmaceuticals

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MENLO PARK, Calif., Dec. 08, 2022 (GLOBE NEWSWIRE) -- Corcept Therapeutics Incorporated (NASDAQ: CORT), a commercial-stage company engaged in the discovery and development of medications to treat severe endocrine, oncologic, metabolic and neurological disorders by modulating the effects of the hormone cortisol, today announced that it has entered into an agreement with Hikma Pharmaceuticals USA Inc. ("Hikma") resolving patent litigation related to Korlym[®], Corcept's medication for the treatment of patients with Cushing's syndrome. The litigation has been pending in the United States District Court for the District of New Jersey since 2021, shortly after Hikma notified Corcept that it had submitted an Abbreviated New Drug Application (ANDA) to the United States Food and Drug Administration (FDA) seeking approval to market a generic version of Korlym.

In connection with the settlement, Corcept has granted Hikma the right to sell a generic version of Korlym in the United States beginning October 1, 2034 or earlier under circumstances customary for settlement agreements of this type.

"It is gratifying to put an end to this litigation," said Joseph K. Belanoff, MD, Corcept's Chief Executive Officer. "Lawsuits are time-consuming diversions from efforts to grow our Korlym business and develop our portfolio of proprietary cortisol modulators, which we have advanced to the clinic as possible treatments for patients with hypercortisolism, solid tumors (including ovarian, adrenocortical and prostate cancer), non-alcoholic steatohepatitis (NASH), antipsychotic-induced weight gain and amyotrophic lateral sclerosis (ALS)."

The settlement agreement is subject to entry by the Court of a consent judgment related to the litigation. As required by law, Corcept and Hikma will submit the agreement to the United States Federal Trade Commission (FTC) and the United States Department of Justice (DOJ) for review. Similar patent litigation brought by Corcept against Teva Pharmaceuticals USA, Inc. remains pending.

About Korlym[®]

Korlym modulates the effect of cortisol at the glucocorticoid receptor, one of the two receptors to which cortisol binds, thereby inhibiting the effects of excess cortisol in patients with Cushing's syndrome. Since 2012, Corcept has made Korlym available as a once-daily oral treatment of hyperglycemia secondary to endogenous Cushing's syndrome in adult patients with glucose intolerance or diabetes mellitus type 2 who have failed surgery or are not candidates for surgery. Korlym was the first FDA-approved treatment for that illness.

About Corcept

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, prostate and adrenal cancer, ALS, weight gain caused by the use of antipsychotic medications and liver disease.

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 concern, but are not limited to, our patents being determined to be invalid or unenforceable or a third party marketing a generic version of Korlym before the conclusion of applicable patent litigation, and the Court, the FTC or the DOJ requiring changes to the settlement agreement. These and other risks are set forth in our SEC filings, which are available at our website and the SEC's website. In this press release, forward-looking statements include statements regarding review of the settlement agreement by the Court, the FTC and the DOJ as well as our ability to grow our Korlym business and advance the development of our selective cortisol modulators, including relacorilant as a potential successor to Korlym. We disclaim any intention or duty to update forward-looking statements made in this press release.

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