



Corcept Therapeutics Receives Orphan Designation for Relacorilant as Treatment for Pancreatic Cancer

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MENLO PARK, Calif., Oct. 01, 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 the Food and Drug Administration (FDA) has granted orphan drug status to Corcept's selective cortisol modulator relacorilant to treat patients with pancreatic cancer. Corcept is conducting clinical trials of relacorilant in combination with nab-paclitaxel (Celgene Corporation's drug, Abraxane[®]) as a treatment for pancreatic cancer and other solid tumors.

Orphan drug designation is granted by the FDA to encourage the development of treatments for diseases that affect fewer than 200,000 patients in the United States. Drugs that receive orphan status obtain seven years of marketing exclusivity from the date of drug approval, tax credits for clinical trial costs, marketing application filing fee waivers and assistance from the FDA in the drug development process. Receiving orphan drug designation does not alter the standard regulatory requirements and process for obtaining marketing approval.

"We are pleased the FDA has granted relacorilant orphan drug status for the treatment of pancreatic cancer. Pancreatic cancer has a poor prognosis and patients have few treatment options," said Joseph K. Belanoff, M.D., Corcept's Chief Executive Officer. "The data we have generated so far in this indication have been very encouraging. Five of nine patients who received the minimum therapeutic dose in our Phase 1/2 trial of relacorilant plus nab-paclitaxel demonstrated durable disease control. By year-end we expect to have learned enough to determine a potential path toward a pivotal study in this indication."

About Pancreatic Cancer

Pancreatic cancer is the fourth leading cause of cancer-associated mortality, with a five-year survival rate of five percent. In the United States, an estimated 33,000 patients are diagnosed with the disease each year.

About Corcept Therapeutics Incorporated

Corcept is engaged in the discovery, development and commercialization of drugs to treat severe metabolic, oncologic and psychiatric disorders by modulating the effects of cortisol. The company has a large portfolio of proprietary compounds, including relacorilant, that selectively modulate the effects of the stress hormone cortisol. It owns extensive United States and foreign intellectual property covering the composition of these compounds and their use to treat a wide variety of serious disorders. Corcept offers its first FDA-approved product, Korlym[®], for the treatment of patients with Cushing's syndrome. The company plans to start a Phase 3 trial of relacorilant to treat patients with Cushing's syndrome by the end of this year.

Abraxane[®] is a trademark of Celgene Corporation.

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