Addition of Relacorilant to Nab-Paclitaxel Improves Progression Free Survival (PFS) in Controlled, Phase 2 trial of 178 Patients with Platinum Resistant Ovarian Cancer

May 6, 2021

- *Women with platinum resistant ovarian cancer experienced longer progression free survival with relacorilant plus nab-paclitaxel than with nab-paclitaxel alone*
- *Women who received a higher dose of relacorilant given "intermittently" together with nab-paclitaxel exhibited a statistically significant improvement in their progression free survival compared to those who received nab-paclitaxel alone (median PFS: 5.6 months versus 3.8 months, hazard ratio: 0.66; p-value: 0.038)*
- *When a lower dose of relacorilant was given daily with nab-paclitaxel, median PFS was 1.5 months longer compared to patients who received nab-paclitaxel alone (5.3 months versus 3.8 months, hazard ratio: 0.83; p-value: NS)*
- *Safety and tolerability of relacorilant plus nab-paclitaxel comparable to nab-paclitaxel monotherapy*
- *Planning underway for Phase 3 pivotal trial*

MENLO PARK, Calif., May 06, 2021 (GLOBE NEWSWIRE) -- Corcept Therapeutics Incorporated (NASDAQ: CORT), a commercial-stage company engaged in the discovery and development of drugs to treat severe metabolic, oncologic and psychiatric disorders by modulating the effects of cortisol, today announced positive results from its 178-patient, controlled, Phase 2 trial of relacorilant plus nab-paclitaxel in patients with recurrent platinum-resistant ovarian cancer.

Women with platinum resistant ovarian cancer (n=60) who received 150 mg of relacorilant the day before, the day of and the day after their weekly nab-paclitaxel infusion exhibited a statistically significant improvement in progression free survival (hazard ratio 0.66, p-value 0.038) compared to women (n=60) who received nab-paclitaxel monotherapy; their median progression free survival was 1.8 months longer (5.6 vs 3.8 months). Safety data and tolerability data for the two groups were comparable. (See Figure 1)

A photo accompanying this announcement is available at https://www.globenewswire.com/NewsRoom/AttachmentNg/04ae9096-0e8c-4248-9473-22c4d4450cb5

A third cohort of patients (n=58) received a daily dose of relacorilant (100 mg per day, with titration to 150 mg per day at the investigator's discretion) in addition to nab-paclitaxel. These patients' median progression-free survival increased 1.5 months compared to the control arm, to 5.3 months, but this improvement did not reach statistical significance (hazard ratio 0.83).

"It's impressive how this therapy extends the benefits of taxanes," said Professor Pamela Munster, MD, Director of the University of California San Francisco's Early Phase Clinical Trials Unit and Co-leader of its Center for BRCA Research. "Patients with platinum-resistant ovarian cancer have few good treatment options. A therapy that significantly extends time to tumor progression without additional side effect burden would be an important advance."

Corcept has begun planning a pivotal Phase 3 trial.

About the Trial

This controlled, multi-center, Phase 2 trial enrolled 178 patients with platinum-resistant ovarian cancer in one of three study arms. Sixty patients received 150 mg relacorilant the day before, the day of and the day after their infusion of nab-paclitaxel. Fifty-eight patients received 100 mg relacorilant every day, with titration up to 150 mg permitted at the investigator's discretion. The sixty patients in the control arm received nab-paclitaxel alone. All patients received nab-paclitaxel on Days 1, 8 and 15 of each 28-day cycle. Patients in the control arm received 100 mg/m^2 of nab-paclitaxel. Because relacorilant increases nab-paclitaxel plasma levels, the nab-paclitaxel dose in patients receiving relacorilant was 80 mg/m^2. The trial's primary endpoint was progression free survival. Secondary endpoints include overall survival, objective response rate and duration of response. The trial is being conducted at 28 sites in the United States and Europe. Additional information about the study (NCT03776812) can be obtained at www.ClinicalTrials.gov.

About Relacorilant

Relacorilant is a non-steroidal, selective modulator of the glucocorticoid receptor that does not bind to the body's other hormone receptors. Corcept is studying relacorilant in a variety of serious disorders, including ovarian, pancreatic and castration-resistant prostate cancer and Cushing's syndrome. Relacorilant is proprietary to Corcept and is protected by composition of matter and method of use patents. It has received orphan drug designation in

the United States for the treatment of Cushing's syndrome and pancreatic cancer.

About Corcept Therapeutics

Corcept is a commercial-stage company engaged in the discovery and development of drugs to treat severe metabolic, oncologic and psychiatric disorders by modulating the effects of the stress hormone cortisol. Korlym® was the first drug approved by the U.S. Food and Drug Administration for patients with Cushing's syndrome. Corcept has discovered a large portfolio of proprietary compounds, including relacorilant, that selectively modulate the effects of cortisol. The company owns extensive United States and foreign intellectual property covering the composition of its selective cortisol modulators and the use of cortisol modulators to treat a variety of serious disorders.

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, the design and results of our clinical trials; our ability to achieve our goals during the COVID-19 pandemic; the development of relacorilant as a treatment for ovarian cancer, including its clinical attributes, regulatory approvals, mandates and oversight, and other requirements; and the scope and protective power of our intellectual property. In this press release, forward-looking statements, include those concerning the clinical attributes of relacorilant and its potential benefits in patients with ovarian cancer, results of our Phase 2 trial and our planning for a Phase 3 pivotal trial. 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.

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Source: Corcept Therapeutics Incorporated

Figure 1

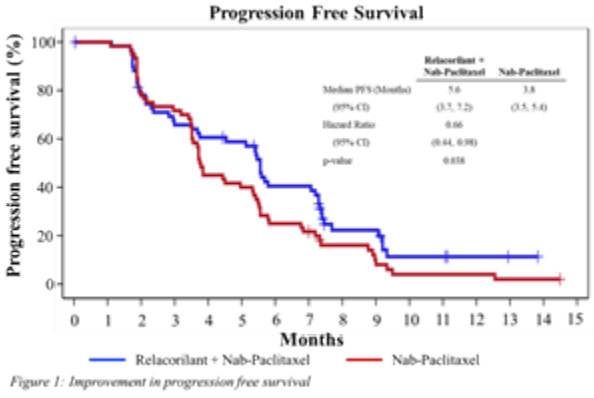

Figure 1: Improvement in progression free survival

Progression Free Survival