Corcept Therapeutics to Start Phase 3 Trial of Relacorilant Plus Nab-Paclitaxel in Patients With Platinum-Resistant Ovarian Cancer

June 6, 2022

Positive results of preceding Phase 2 trial to be featured in oral presentation at the American Society of Clinical Oncology (ASCO) Annual Meeting

MENLO PARK, Calif., June 06, 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, following consultation with the U.S. Food and Drug Administration (FDA), it will start a registrational Phase 3 trial of relacorilant plus nab-paclitaxel in patients with recurrent, platinum-resistant ovarian cancer. The company also announced that the positive results from its 178-patient, randomized, controlled, Phase 2 study will be featured in an oral presentation at the American Society of Clinical Oncology (ASCO) Annual Meeting today.

“We are excited to launch our pivotal Phase 3 trial, which we have named ROSELLA,” said Bill Guyer, PharmD, Corcept’s Chief Development Officer. “Simply replicating the positive results of our Phase 2 study – improvements in progression free survival, duration of response and overall survival without increased side effect burden – will be of unprecedented benefit to women with advanced ovarian cancer, for whom relacorilant plus nab-paclitaxel has the potential to become a new standard of care.”

“The ROSELLA trial design closely tracks the design of our successful Phase 2 study, with adjustments that emerged from constructive conversations with the FDA and leading clinicians from the Gynecological Oncology Group. Based on these conversations, we are confident that positive results in ROSELLA will support a new drug application.”

ROSELLA has a planned enrollment of 360 women, randomized 1:1 to receive either relacorilant plus nab-paclitaxel or nab-paclitaxel monotherapy. The primary endpoint will be progression free survival, with overall survival as a key secondary endpoint.

All patients will have received prior bevacizumab therapy, which is the current standard of care in the United States for patients with platinum-resistant ovarian cancer. Almost two-thirds of the women enrolled in Corcept’s Phase 2 trial met this criterion. Women with a history of tumors that do not respond at all to initial platinum-based treatments (i.e., women with “primary platinum-refractory” disease) and those who have received more than three prior lines of therapy – both indicators of a very poor prognosis – will be excluded.

Corcept plans to start ROSELLA by the end of this month.

In Corcept’s Phase 2 trial, women who met the entry criteria for ROSELLA and received relacorilant exhibited substantial benefit, without increasing the frequency or severity of adverse events. Results for patients who received relacorilant at the time they received nab-paclitaxel – the “intermittent” dosing regimen that will be used in ROSELLA – are set forth in Table 1.

Phase 2 Trial Results (ROSELLA Patient Population)			
	Relacorilant + Nab-paclitaxel n=25	***Comparator n=31***	***Hazard Ratio (95% CI)***
Progression-Free Survival *(median)*	7.3 months	3.7 months	0.40 (0.21, 0.77); p = 0.005
Duration of Response *(median)*	5.6 months	3.1 months	0.29 (0.09, 0.99); p = 0.016
Overall Survival *(median)*	17.9 months	12.6 months	0.38 (0.17, 0.82); p = 0.011

Table 1: Results for women in the intermittent and comparator arms of the Phase 2 trial who met the ROSELLA entry criteria.

The Kaplan-Meyer curve showing the survival benefit experienced by women in the Phase 2 trial’s intermittent arm and who met the ROSELLA entry criteria is set forth in Figure 1.

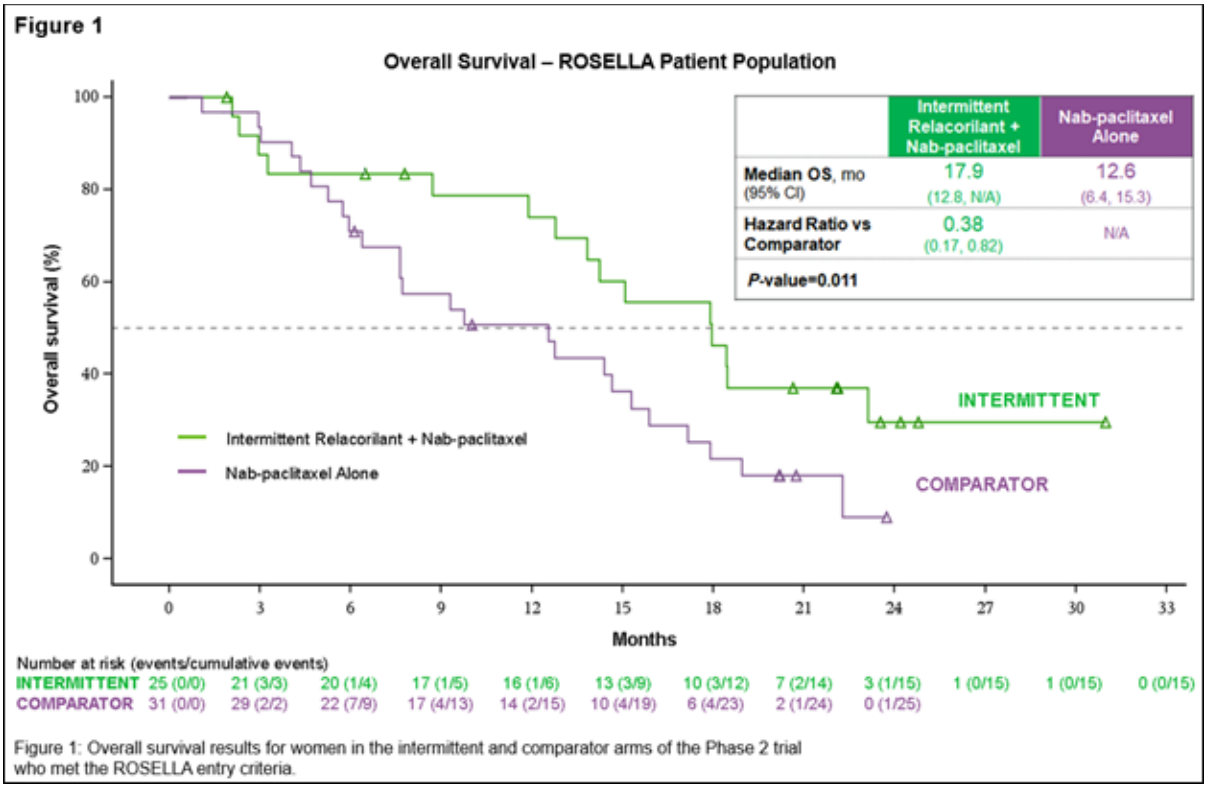

Figure 1: Overall survival results for women in the intermittent and comparator arms of the Phase 2 trial who met the ROSELLA entry criteria.

ASCO Oral Presentation

Results from the company's Phase 2 study in patients with recurrent, platinum-resistant ovarian cancer will be featured in an oral presentation at the ASCO Annual Meeting today. Presentation slides are available at www.corcept.com/research-pipeline/publications.

Presentation Title: "Overall survival data from a 3-arm, randomized, open-label, phase 2 study of relacorilant, a selective glucocorticoid receptor modulator, combined with nab-paclitaxel in patients with recurrent platinum-resistant ovarian cancer."

Speaker: Dr. Nicoletta Colombo; University of Milan-Bicocca and European Institute of Oncology, IRCCS

Presentation Time / Location: Monday, June 6, 2022, 9:00 AM - 9:12 AM CDT / E450

About Platinum-Resistant Ovarian Cancer

Ovarian cancer is the fifth most common cause of cancer death in women.[1] Patients whose disease returns less than six months after receiving platinum-containing therapy are described as having "platinum-resistant" disease. In the United States, approximately 20,000 women with platinum-resistant disease are candidates to start a new therapy each year.[2] There are few treatment options and median overall survival following recurrence of disease is 12 months or less with single-agent chemotherapy.[3] No approved therapy has been shown to significantly extend overall survival in patients with recurrent, platinum-resistant ovarian cancer compared to standard chemotherapy.[4]

About Corcept's Oncology Programs

There is substantial evidence that cortisol activity at the glucocorticoid receptor ("GR") reduces the efficacy of certain anti-cancer therapies and that modulating cortisol's activity may help anti-cancer treatments achieve their intended effect.

Many types of solid tumors express the GR and are potential targets for cortisol modulation therapy. In some cancers, cortisol inhibits cellular apoptosis – the tumor-killing effect many treatments are meant to stimulate. In other cancers, cortisol activity promotes tumor growth. Cortisol also suppresses the body's immune response; activating – not suppressing – the immune system is beneficial in fighting certain cancers.

Corcept is conducting clinical trials of its proprietary selective cortisol modulators in combination with three different anti-cancer treatments in patients with ovarian, adrenal and prostate cancers. Corcept's first controlled study in oncology – relacorilant plus nab-paclitaxel for the treatment of patients with ovarian cancer – has demonstrated statistically significant and clinically meaningful results.

About Relacorilant

Relacorilant is a non-steroidal, selective glucocorticoid receptor modulator that does not bind to the body's other hormone receptors. Corcept is studying relacorilant in a variety of serious disorders, including ovarian and adrenal cancer and Cushing's syndrome. Relacorilant is proprietary to Corcept and is protected by composition of matter and method of use patents, as well as orphan drug designation in the United States for the treatment of pancreatic cancer and both the United States and the European Union for the treatment of Cushing's syndrome.

About Corcept Therapeutics

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, adrenal and prostate cancer, weight gain caused by the use of antipsychotic medications and liver disease. Corcept's drug Korlym ® was the first medication approved by the U.S. Food and Drug Administration for the treatment of patients with Cushing's syndrome.

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 include, but are not limited to, our ability to operate our business, conduct our clinical trials and achieve our other goals during the COVID-19 pandemic; risks related to the development of relacorilant and other product candidates, including their clinical attributes, regulatory approvals, mandates, oversight and other requirements; and the scope and protective power of our intellectual property. 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 those concerning the development of relacorilant as a treatment for ovarian cancer, including its clinical attributes, regulatory approvals, mandates and oversight, and other requirements; the potential for relacorilant plus nab-paclitaxel to become a standard of care for patients with recurrent platinum-resistant ovarian cancer; our planned Phase 3 trial, including its design and start date, results and the probability of its success as a registrational study. We disclaim any intention or duty to update forward-looking statements made in this press release.

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[1] American Cancer Society (www.cancer.org)
[2] Clarivate | Decision Resources Group Ovarian Cancer Market Forecast Dashboard - December 2021 (www.clarivate.com)
[3] *Therapeutic Advances in Medical Oncology* (Luvero et al. 2014)
[4] *Journal of Clinical Oncology* (Pujade-Lauraine et al. 2014)

A photo accompanying this announcement is available at https://www.globenewswire.com/NewsRoom/AttachmentNg/4642fad3-bdfc-43ed-b1e5-e99d42d5c8cc

Source: Corcept Therapeutics Incorporated

Figure 1

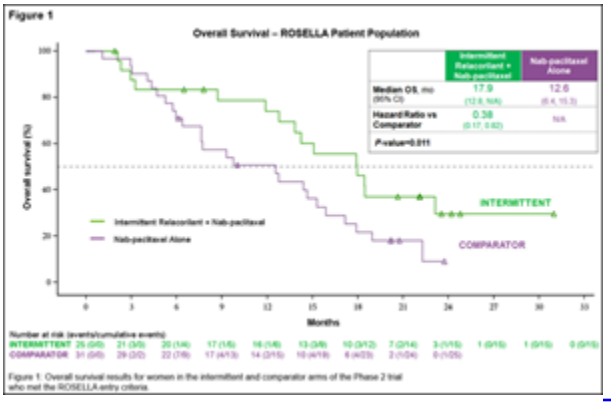

Figure 1