Corvus Pharmaceuticals Announces Preclinical and Preliminary Clinical Biomarker Data of Lead Oral Checkpoint Inhibitor CPI-444 Presented at Second CRI-CIMT-EATI-AACR International Cancer Immunotherapy Conference

--Preclinical Studies Demonstrate Activity of CPI-444 Both Alone and in Combination with Anti-PD-1 and Anti-PD-L1 Antibodies--

--Preliminary Phase 1/1b Clinical Biomarker Data Show Complete Blockade of Peripheral Blood Lymphocyte A2A Receptors in Dose-Dependent Manner and Induction of Activated T-Cells--

BURLINGAME, Calif., Sept. 25, 2016 (GLOBE NEWSWIRE) -- Corvus Pharmaceuticals, Inc. (NASDAQ:CRVS), a clinical-stage biopharmaceutical company focused on the development and commercialization of novel immuno-oncology therapies, today announced preclinical data as well as preliminary biomarker data from its ongoing Phase 1/1b study of CPI-444 as a single agent and in combination with Genentech’s TECENTRIQ™ (atezolizumab), a fully humanized monoclonal antibody targeting protein programmed cell death ligand 1 (PD-L1). CPI-444 is a selective and potent inhibitor of the adenosine A2A receptor. The data were presented today in both oral and poster presentations by Stephen Willingham, Ph.D., Corvus senior scientist, at the Second CRI-CIMT-EATI-AACR International Cancer Immunotherapy Conference: Translating Science into Survival, which is taking place in New York at the Sheraton New York Times Square Hotel and the New York Hilton Midtown.

“We are very encouraged by the early data showing that CPI-444 is well tolerated and by the biomarker data indicating that treatment with CPI-444 as a single agent is associated with activation of T-cells detected in the blood. We believe this is the first demonstration of immune modulation in cancer patients receiving an adenosine antagonist,” said Richard A. Miller, M.D., an oncologist and co-founder, president and chief executive officer of Corvus. “Patient enrollment in our CPI-444 Phase 1/1b study is on schedule, and we anticipate completing the dose-selection portion of the study and reporting interim safety and efficacy data at a scientific conference later this year. That data will enable us to choose the best dose for testing in disease-specific expansion cohorts, which we expect to initiate before year end.”

According to preclinical study results presented at the Conference:

- CPI-444 has been shown to be active, both as a single agent and in combination with anti-PD-1 and anti-PD-L1 antibodies, in stimulating various immune cells, generating anti-tumor immunity, suppressing tumor growth, delaying tumor progression and generating complete tumor rejection in multiple animal models of cancer.
- Results from mechanism of action studies indicate that CD8+ cytotoxic T-lymphocytes are necessary for CPI-444’s activity in animal models.
- Long-term immunity was demonstrated upon tumor re-challenge in animals previously treated with CPI-444.

Preliminary biomarker data from ongoing analyses of patients with various solid tumors treated to date in the ongoing Phase 1/1b study presented at the Conference demonstrated:

- In the first 11 patients analyzed, 40-100 percent blockade of peripheral blood lymphocyte
A2A receptors was achieved in a dose-dependent manner with CPI-444 treatment.

- All three patients receiving CPI-444 100 mg twice daily for 28 days achieved 90-100 percent continuous, sustained blockade of peripheral blood lymphocyte A2A receptors.
- Pharmacodynamic markers on peripheral blood lymphocytes showed evidence of activation of T-cell mediated immunity in all three patients treated with CPI-444 100 mg twice daily for 28 days. In these patients, increases in cytotoxic T-lymphocytes that were both PD-1-positive and CD8-positive (double positive) were seen in the blood following 28 days of treatment compared to baseline pretreatment. Previous research from others has shown that PD-1, CD8 double positive T-cells are associated with anti-tumor immune responses.
- CPI-444 has been well tolerated to date, with no drug-related dose limiting toxicities or serious adverse events observed.
- The trial is currently enrolling patients at 25 sites in the United States, Canada and Australia with 39 patients enrolled to date.

About the Phase 1/1b Trial

The Phase 1/1b trial is designed to examine the activity of CPI-444 as a single agent and in combination with Genentech’s TECENTRIQ (atezolizumab), an anti-PD-L1 antibody. The first part of the study (dose-selection) includes four cohorts of 12 patients each – three cohorts treated with single agent CPI-444 (100 mg twice daily for 14 days; 100 mg twice daily for 28 days; 200 mg once daily for 14 days) and one cohort treated with the combination (CPI-444 50 mg or 100 mg twice daily for 14 days combined with TECENTRIQ). A treatment cycle is 28 days. Patients with non-small cell lung cancer, melanoma, renal cell cancer, triple-negative breast cancer, colorectal cancer, head and neck cancer, bladder cancer and prostate cancer who have failed all standard therapies are eligible. Based on safety and biomarker analyses, an optimum single agent and combination dose will be selected. The second part of the study will evaluate CPI-444 as a single agent in five disease-specific cohorts, and CPI-444 in combination with TECENTRIQ in five additional matched disease-specific cohorts. Corvus expects that each of these 10 cohorts will initially enroll 14 patients, but each cohort may be expanded based on efficacy.

About Corvus Pharmaceuticals

Corvus Pharmaceuticals is a clinical-stage biopharmaceutical company focused on the development and commercialization of small molecule and antibody agents that target the immune system to treat patients with cancer. These agents block or modify crucial immune checkpoints and reprogram immune T-cells. Corvus’ lead product, CPI-444, is a checkpoint inhibitor that is designed to disable a tumor’s ability to subvert attack by the immune system by inhibiting adenosine in the tumor microenvironment. CPI-444 is a small molecule that is taken orally. CPI-444 is currently being evaluated in a multicenter Phase 1/1b clinical trial in patients with various solid tumors. This successive expansion cohort trial is examining the activity of CPI-444 both as a single agent and in combination with Genentech’s TECENTRIQ (atezolizumab), an anti-PD-L1 antibody. Corvus is conducting the trial with Genentech, a member of the Roche Group, under a clinical trial collaboration the two companies entered into in October 2015. For more information, visit: www.corvuspharma.com.

Forward-Looking Statements

This press release contains forward-looking statements, including statements related to the potential efficacy of CPI-444, both as a single agent and in combination with anti-PD-1 or anti-PD-L1, the Company’s ability to develop and advance product candidates into, and successfully complete, clinical trials, the timing and successful completion of the Company’s Phase 1/1b clinical trial for CPI-444, and the utility of biomarker data collected in such clinical trial. All statements other than statements of historical fact contained in this press release are forward-looking statements. These statements often include words such as “believe,” “expect,” “anticipate,” “intend,” “plan,” “estimate,” “seek,” “will,” “may” or similar expressions. Forward-looking statements are subject to a number of risks and uncertainties, many of which involve factors or circumstances that are beyond the Company’s control. The Company’s actual results could differ...
materially from those stated or implied in forward-looking statements due to a number of factors, including but not limited to, risks detailed in the Company’s registration statement on Form S-1 filed with the Securities and Exchange Commission, as well as other documents that may be filed by the Company from time to time with the Securities and Exchange Commission. In particular, the following factors, among others, could cause results to differ materially from those expressed or implied by such forward-looking statements: the Company’s ability to utilize biomarker data and demonstrate evidence of efficacy and safety for CPI-444 during its Phase 1/1b clinical trial; the accuracy of the Company’s estimates relating to its ability to initiate and/or complete clinical trials; the unpredictability of the regulatory process; regulatory developments in the United States and foreign countries. Although the Company believes that the expectations reflected in the forward-looking statements are reasonable, it cannot guarantee that the events and circumstances reflected in the forward-looking statements will be achieved or occur, and the timing of events and circumstances and actual results could differ materially from those projected in the forward-looking statements. Accordingly, you should not place undue reliance on these forward-looking statements. All such statements speak only as of the date made, and the Company undertakes no obligation to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise.

Investor Contact:
Jason Coloma, Ph.D.
SVP and Chief Business Officer
650-900-4511
JColoma@corvuspharma.com

Media Contact:
Julie Normart, W2O Group
415-946-1087
jnormart@w2ogroup.com