

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549**

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934
Date of Report (Date of earliest event reported): November 11, 2017

CORVUS PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-37719
(Commission
File Number)

46-4670809
(IRS Employer
Identification Number)

863 Mitten Road, Suite 102
Burlingame, CA 94010
(Address of principal executive offices, including Zip Code)

Registrant's telephone number, including area code: (650) 900-4520

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2). Emerging growth company [X]

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. [X]

Item 8.01. Other Events.

On November 11, 2017, Corvus Pharmaceuticals, Inc. (“Corvus” or the “Company”) issued a press release announcing updated clinical data from its Phase 1/1b study of CPI-444 and biomarker data for potential use in patient selection. The full text of the press release is filed as Exhibit 99.1 hereto and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
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99.1	Press release titled, “Corvus Pharmaceuticals Announces Updated Clinical Data from Phase 1/1b Study of CPI-444 and Biomarker Data for Potential Use in Patient Selection” dated November 11, 2017.
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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

CORVUS PHARMACEUTICALS, INC.

Date: November 11, 2017

By: /s/ Leiv Lea
Leiv Lea
Chief Financial Officer

Corvus Pharmaceuticals Announces Updated Clinical Data from Phase 1/1b Study of CPI-444 and Biomarker Data for Potential Use in Patient Selection

*– Clinical Data from Renal Cell Carcinoma Cohorts Presented
in Oral Session at SITC 32nd Annual Meeting –*

*– Adenosine Pathway Gene Expression Associated with
Response to Therapy and Resistance to Prior Anti PD-(L)-1 –*

BURLINGAME, Calif., Nov. 11, 2017 (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 updated clinical data from the renal cell carcinoma (RCC) expansion cohorts of its ongoing Phase 1/1b study of CPI-444 as a single agent and in combination with atezolizumab (TECENTRIQ[®]). Results showed a response rate of 14 percent (two partial responses, one of which was unconfirmed) with single agent CPI-444 and 13 percent (two confirmed partial responses) for the combination therapy, and a disease control rate of 29 percent and 69 percent for single agent and combination therapy, respectively, in 30 response-evaluable patients. Additionally, biomarker data from the trial showed an association between adenosine pathway gene expression and response to therapy, and resistance to prior anti-PD-(L)1 treatment. The clinical and biomarker data were presented today in an oral session at the Society for Immunotherapy of Cancer's (SITC) 32nd Annual Meeting in National Harbor, Md., by Jason J. Luke, M.D., a medical oncologist and assistant professor of medicine at the University of Chicago Medicine.

CPI-444 is a selective and potent inhibitor of the adenosine A2A receptor. Atezolizumab, developed by Genentech, a member of the Roche Group, is a monoclonal antibody designed to target and bind to a protein called PD-L1 (programmed death ligand-1).

“These data provide new information on the importance of the adenosine pathway and its value as a target for cancer immunotherapy,” said Dr. Luke. “We are seeing clinical activity in patients with RCC and other tumors, including patients who are resistant to prior anti-PD-(L)1 therapy and have few treatment options. The early biomarker data show that prior exposure to anti-PD-(L)1 increases expression of adenosine pathway genes, supporting earlier research indicating that the adenosine pathway is a resistance mechanism to anti-PD-(L)1 therapy. The data suggest that it may be possible to use biomarkers, specifically tumor expression of the A2A receptor and CD73, to identify patients with RCC and other tumors who are most likely to respond to treatment with CPI-444 or other forms of adenosine blockade.”

The ongoing Phase 1/1b clinical trial has enrolled more than 225 patients with several tumor types including RCC, non-small cell lung cancer (NSCLC), triple negative breast cancer (TNBC), melanoma and other tumors. To date, RCC (single agent and combination) and NSCLC (single agent and combination) cohorts have met the protocol-defined criteria for expansion from 14 to 26 patients. For both the RCC single agent and combination cohorts, criteria for expansion to 48 patients per cohort have been reached. Of 51 patients with RCC enrolled in the study, 69 percent were resistant or refractory to prior anti-PD-(L)1 therapy, having failed those therapies within a median time of 1.6 months prior to enrollment. The RCC patients had several adverse prognostic features including visceral metastases (88 percent), hepatic metastases (20 percent), anemia (45 percent) and elevated serum lactate dehydrogenase (21 percent).

“Our Phase 1/1b study continues to generate important clinical and biologic data that is helping us identify mechanisms of resistance to anti-PD-(L)1 therapies. With that data, we may be able to identify clinical characteristics and biomarkers associated with a clinical response, optimize treatment regimens and improve patient outcomes,” said Richard A. Miller, an oncologist and co-founder, president and chief executive officer of Corvus. “In 2018, we anticipate initiating a pivotal trial of CPI-444 in RCC and, utilizing the information we have learned to date, selecting patients most likely to benefit from treatment. We also intend to initiate a clinical trial of our anti-CD73 antibody in the first half of 2018, which is another approach to blockade of the adenosine pathway in RCC and other cancers.”

Key Clinical Results Presented at SITC

Updated efficacy and safety data from the single agent and combination RCC cohorts were presented at SITC. 51 patients with RCC have been enrolled to date. Data from 14 patients receiving CPI-444 single agent therapy and 16 receiving combination therapy who were evaluable for response showed:

- Four patients experienced a partial response (one confirmed and one unconfirmed with single agent therapy and two confirmed partial responses with combination). Both single agent responses occurred in patients resistant or refractory to prior treatment with anti-PD-(L)1.
- Disease control (stable disease and partial responses) was achieved in 29 percent and 69 percent of patients receiving single agent and combination therapy, respectively.
- CPI-444 continues to be well tolerated to date, with observed adverse events similar to previous reports. In both the single-agent and combination arms for the entire safety data set (N=210), Grade 1 and 2 adverse events occurring in 5 or more percent of patients included fatigue, nausea, pruritis, pyrexia, decreased appetite, diarrhea and anemia. One patient had Grade 3 nausea, vomiting and diarrhea in the single agent arm. Four patients had a serious Grade 3 toxicity in the combination arm, one with hepatitis, one with pneumonitis, one with hemolytic anemia, and one with hepatitis, mucositis, pneumonitis and dermatitis. One other patient in the combination arm had both Grade 4 encephalitis and Grade 3 thrombocytopenia.

Key Biomarker Results Presented at SITC

Biomarker analysis, performed on blood and tumor tissues from the RCC and NSCLC cohorts, showed:

- Tumor expression of the A2A receptor, CD73 and CD39 was increased in patients resistant to prior treatment with anti-PD-(L)1.
- Patients with RCC and NSCLC had high tumor expression of the A2A receptor, CD73 and CD39 in screening, pre-treatment biopsies compared to patients with other tumors.
- Biopsies showed that treatment with CPI-444 increased CD8 positive cell infiltration in tumors and induced expression of genes consistent with Th1 activation.

For patients enrolled in the study with all tumor histologies and for whom screening biopsies were available for analysis, tumor expression of the A2A receptor and CD73 was associated with a response to CPI-444, as follows:

- Patients with high expression of the A2A receptor had a disease control rate of 29 percent (10 of 34) compared with 10 percent (four of 39) for those with low expression.
- Patients with high expression of CD73 had a disease control rate of 24 percent (12 of 51) compared with 9 percent (two of 22) for those with low expression.
- Patients with high expression of both the A2A receptor and CD73, referred to as *double positive*, had a disease control rate of 42 percent (10 of 24) compared to 8 percent for those without double positive tumors (four of 47), $p < 0.0007$.
- All four of the patients with a partial response were double positive (two RCC patients, one NSCLC patient and one MSI-H colon cancer patient). Tissue was not available for all patients with a partial response.

Phase 1/1b Trial Design

The Phase 1/1b trial is designed to select the dose, assess the safety and examine the activity of CPI-444 as a single agent and in combination with Genentech's atezolizumab, an anti-PD-L1 antibody, in multiple histologies known to be sensitive to immunoncology agents. Patients with non-small cell lung cancer, melanoma, renal cell cancer, triple-negative breast cancer, MSI-H colorectal cancer, head and neck cancer, bladder cancer and prostate cancer who have failed standard therapies are eligible. The efficacy endpoints of the study are response rate and disease control rate, which is defined as complete response, partial response (reduction of >30 percent tumor volume) or stable disease (change in tumor volume of between 20 percent growth of tumor and 30 percent reduction of tumor volume). Patients with minor tumor regressions are those with changes in tumor volume of 0 to ≤30 percent reduction in tumor volume. Patients are treated until disease progression or evidence of Grade 3 or 4 toxicity.

The dose-selection part of the study included four cohorts of 12 patients each (N=48) – 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 atezolizumab). A treatment cycle is 28 days. Based on biomarker analyses showing sustained, complete blockade of the adenosine A2A receptor in peripheral blood lymphocytes, and evidence of immune activation in circulating lymphocytes, an optimum single agent and combination dose of 100 mg twice a day for 28 days was selected for the second part of the study. As defined in the protocol, patients in the dose-selection stage of the trial receiving the dose and schedule selected for evaluation in the second part of the study are included in the disease-specific cohort efficacy analysis.

The second part of the study is evaluating CPI-444 as a single agent in five disease-specific cohorts (NSCLC, melanoma, RCC, TNBC and a category of "other" that includes MSI-H colorectal cancer, bladder cancer and prostate cancer) and CPI-444 in combination with atezolizumab in five additional matched disease-specific cohorts. Each of the 10 cohorts is initially enrolling 14 patients, but may be expanded based on efficacy.

About CPI-444

CPI-444 is a small molecule, oral, checkpoint inhibitor designed to disable a tumor's ability to subvert attack by the immune system by blocking the binding of adenosine in the tumor microenvironment to the A2A receptor. Adenosine, a metabolite of ATP (adenosine tri-phosphate), is produced within the tumor microenvironment where it may bind to the adenosine A2A receptor present on immune cells and block their activity. CD39 and CD73 are enzymes on the surface of tumor cells and immune cells. These enzymes work in concert to convert ATP to adenosine.

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. Corvus' lead product, 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 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.

TECENTRIQ® (atezolizumab) is a registered trademark of Genentech.

Forward-Looking Statements

This press release contains forward-looking statements, including statements related to the potential safety and efficacy of CPI-444, both as a single agent and in combination with anti-PD-1, anti-PD-L1, or other therapies, the Company's ability to develop and advance product candidates into and successfully complete clinical trials, including the Company's Phase 1/1b clinical trial of CPI-444, the basis for any future clinical trials with CPI-444, the utility of biomarker data collected and the suitability of the dosing regimen selected for the Company's Phase 1/1b clinical trial of CPI-444. 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 Quarterly Report on Form 10-Q for the nine months ended September 30, 2017, filed with the Securities and Exchange Commission on November 2, 2017, 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 results of early clinical trials may not be predictive of future results; the unpredictability of the regulatory process; and 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.

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