

**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 10, 2018

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

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.

Item 7.01. Regulation FD Disclosure.

On November 10, 2018, Corvus Pharmaceuticals, Inc. issued a press release announcing updated results from ongoing clinical studies of its lead programs, CPI-444 and CPI-006. The full text of the press release is furnished as Exhibit 99.1 hereto and is incorporated herein by reference.

The information in this Item 7.01, including Exhibit 99.1, shall not be deemed “filed” for purposes of Section 18 of the Security Exchange Act of 1934, as amended (the “Exchange Act”) or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01. Financial Statements and Exhibits.

| <u>Exhibit No.</u> | <u>Description</u> |
|--------------------|--|
| 99.1 | Press release titled, “Corvus Pharmaceuticals Announces Updated Results from Ongoing Clinical Studies of Lead Programs, CPI-444 and CPI-006, at SITC 33rd Annual Meeting” dated November 10, 2018. |

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 13, 2018

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

Corvus Pharmaceuticals Announces Updated Results from Ongoing Clinical Studies of Lead Programs, CPI-444 and CPI-006, at SITC 33rd Annual Meeting

CPI-444 demonstrated prolonged survival in patients with refractory renal cell carcinoma both as a monotherapy and in combination with atezolizumab

Novel adenosine gene signature biomarker associated with response to CPI-444 therapy

CPI-006 early clinical data showed evidence of immune activation of B cells and effect on lymphocyte trafficking

BURLINGAME, Calif., Nov. 10, 2018 (GLOBE NEWSWIRE) -- Corvus Pharmaceuticals, Inc. (NASDAQ: CRVS), a clinical-stage biopharmaceutical company focused on the development and commercialization of precisely targeted oncology therapies, today announced updated clinical and biomarker data from ongoing Phase 1/1b studies of its lead programs, CPI-444 and CPI-006. Updated results from its Phase 1/1b clinical trial of CPI-444 in patients with treatment-refractory renal cell carcinoma (RCC) demonstrated an overall survival (OS) of 88 percent at more than 20 months follow-up with CPI-444 administered in combination with atezolizumab. The clinical data were presented in an oral session at the Society for Immunotherapy of Cancer's (SITC) 33rd Annual Meeting in Washington, D.C., by Lawrence Fong, M.D., study investigator and leader of the Cancer Immunotherapy Program at the University of California, San Francisco (UCSF) Helen Diller Family Comprehensive Cancer Center.

Additionally, CPI-444 biomarker data from the Phase 1/1b study showing that expression of a novel adenosine gene signature was significantly associated with tumor regression were presented both in the oral presentation and in a poster session at the SITC meeting. Early clinical data from an ongoing Phase 1/1b study evaluating CPI-006 as a monotherapy showing evidence of immune activation of B cells were presented in a poster session.

CPI-444, Corvus' lead product candidate, is a selective and potent inhibitor of the adenosine A2A receptor. It is currently being evaluated in Phase 1/1b and 1b/2 clinical trials in patients with various solid tumors as a monotherapy and in combination with Genentech's atezolizumab, an anti-PD-L1 antibody. CPI-006 is a humanized monoclonal antibody directed against CD73. It is currently being evaluated in a Phase 1/1b three-arm clinical trial in patients with a variety of solid tumors as a monotherapy, in combination with CPI-444, and in combination with pembrolizumab, an anti-PD-1 antibody.

"The newest data on our two lead programs further establish a promising foundation for the application of adenosine blockade in cancer therapy," said Richard A. Miller, M.D., an oncologist and co-founder, president and chief executive officer of Corvus. "The longer-term follow-up data from our Phase 1/1b study of CPI-444 showed objective tumor responses and prolonged survival in a larger group of patients with treatment-refractory RCC, which is highly encouraging given such advanced disease."

He added, "With this study, we also discovered an adenosine gene signature that can be obtained from tumor biopsies and potentially could be used as a predictive biomarker for patient selection. This signature is expected to be an important factor as we design our CPI-444 pivotal trials. Furthermore, the biomarker and clinical data in anti-PD-(L)1 resistant, refractory patients enhance our understanding of the tumor biology. By blocking adenosine in the tumor microenvironment from binding with the A2A receptor, CPI-444 enables anti-PD-(L)1 therapies to stimulate T cell function to attack cancer cells. The biomarker data add to our understanding of the mechanism of action, which makes combination therapy very attractive since CPI-444 appears to inhibit an important anti-PD-(L)1 resistance mechanism."

Key CPI-444 Clinical Results Presented at SITC

Study investigator Dr. Fong presented updated efficacy and safety data at SITC from the ongoing Phase 1/1b clinical study of CPI-444 in RCC patients with progressive disease (presentation slides available on the Corvus website in the "Publications and Presentations" section, which can be found here). Study participants had advanced refractory disease and a poor prognosis. They had been treated with a median of three prior therapies (range: 1 to 5), and approximately 72 percent had failed prior anti-PD-(L)1 therapy. For more than 60 percent of patients, the protocol treatment represented a fourth, fifth or sixth line of therapy. Data from 33 patients receiving CPI-444 as a monotherapy and 35 receiving CPI-444 in combination with atezolizumab who were evaluable for response showed:

- Disease control for more than 6 months was achieved in 35 percent and 17 percent of patients receiving combination therapy and monotherapy, respectively.
- For patients receiving combination therapy, 11 percent experienced a confirmed partial response (PR; as determined by RECIST criteria). Several additional patients experienced tumor regression not meeting the criteria for a PR. For patients receiving monotherapy, one patient experienced a confirmed PR, one experienced an unconfirmed PR, and several patients experienced tumor regression not meeting the PR criteria.
- Responses were seen in both the combination therapy and monotherapy arms, and in patients who failed prior anti-PD-(L)1 therapy.
- Progression-free survival (as assessed by RECIST criteria) was 5.9 months with combination therapy and 4.0 months with monotherapy.
- OS was 88 percent at 20+ months with combination therapy and 65 percent at 16+ months with monotherapy.
- Combination therapy was superior to monotherapy with respect to OS, response rate, disease control rate and progression-free survival.
- Evaluation of pre- and on-treatment tumor biopsies showed a statistically significant correlation between treatment-induced CD8+ T cell infiltration in tumors and response ($p < 0.016$).

- The recently described adenosine signature showed a statistically significant correlation with tumor response and disease control rates ($p < 0.008$).
- CPI-444 continues to be well tolerated to date, with observed adverse events similar to previous reports. In the combination arm, adverse events were generally consistent with other anti-PD-L1 therapies. In the monotherapy arm, grade 3 adverse events were infrequent and reversible.

Key CPI-444 Biomarker Results Presented at SITC

Biomarker analysis, performed on tumor tissue from biopsies of 30 RCC patients treated with monotherapy or combination therapy in the ongoing Phase 1/1b study of CPI-444, showed:

- Expression of the adenosine gene signature in pre-treatment tumor biopsies was significantly associated with tumor response to treatment with CPI-444 ($p < 0.008$).
- The adenosine gene signature identified a group of chemokines and cytokines that are associated with myeloid-derived suppression.
- Adenosine induces the production of these chemokines and cytokines, which inhibit anti-tumor immunity. CPI-444 blocks the production of these substances.

“Our other lead program, CPI-006, is different from other previously described anti-CD73 antibodies that we are aware of,” said Joseph J. Buggy, Ph.D., co-founder and executive vice president of research of Corvus. “Early clinical data from our Phase 1/1b trial presented at SITC showed that CPI-006 inhibited CD73 enzymatic activity and stimulated intracellular signaling to activate B cells, which appears to cause the migration of lymphocytes to lymphoid tissues. This activity is independent of adenosine and could be important in stimulating anti-tumor immunity.”

Key CPI-006 Clinical Results Presented at SITC

Initial data from an ongoing Phase 1/1b clinical trial of CPI-006 administered as a monotherapy or as combination therapy in patients with various cancers who have failed standard therapies were presented at SITC. Results from nine patients who received ascending doses of CPI-006 (1, 3 and 6 mg/kg; N=3 at each dose) showed that CPI-006:

- Targeted a novel epitope on CD73
- Blocked production of adenosine by inhibiting the enzymatic active site of CD73
- Activated peripheral blood B cells leading to increased expression of CD69 independent of adenosine
- Affected B lymphocyte trafficking as shown by transient decreases of circulating B cells
- Was well tolerated at the doses evaluated with no dose-limiting toxicities

In this study, dose escalation continues with CPI-006 as a monotherapy and in combination with the adenosine A2A receptor antagonist CPI-444.

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. In vitro and preclinical studies have shown that dual blockade of CD73 and the A2A receptor may be synergistic.

About CPI-006

CPI-006 is a potent humanized monoclonal antibody that reacts with the active site of CD73, blocking the conversion of AMP to adenosine. In vitro studies of CPI-006 have shown it is capable of substantially inhibiting the production of adenosine by blocking the CD73 enzyme. Clinical study results have indicated that CPI-006 has also stimulated activation of lymphoid cells in an adenosine-independent manner.

About Corvus Pharmaceuticals

Corvus Pharmaceuticals is a clinical-stage biopharmaceutical company focused on the development and commercialization of precisely targeted oncology therapies. Corvus’ lead product candidate, CPI-444, a small molecule inhibitor of the A2A receptor, 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. In May 2017, Corvus and Genentech expanded the collaboration and are now conducting a trial of CPI-444 and atezolizumab in patients with non-small cell lung cancer (NSCLC) who have failed prior therapies with anti-PD-(L)1 and platinum-based chemotherapy. Corvus is evaluating a second product candidate, CPI-006, a humanized monoclonal antibody directed against CD73, in a multicenter Phase 1/1b clinical trial in patients with various solid tumors. For more information, visit www.corvuspharma.com.

FORWARD-LOOKING STATEMENTS

This press release contains forward-looking statements, including statements related to the potential safety and efficacy of CPI-444 and CPI-006, the Company’s ability to develop and advance product candidates into and successfully complete preclinical studies and clinical trials, including the Company’s Phase 1/1b clinical trial of CPI-444 and the Company’s Phase 1/1b clinical trial of CPI-006 and the utility of biomarker data collected. 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 quarter ended September 30, 2018, filed with the Securities and Exchange Commission on November 1, 2018, 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 demonstrate sufficient evidence of efficacy and safety in its clinical trials of CPI-444 and CPI-006; the Company’s ability to utilize biomarker data; the results of preclinical studies 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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