CytomX Therapeutics, Inc.
Form 8-K
June 04, 2018

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): June 4, 2018

CYTOMX THERAPEUTICS, INC.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-37587**	**27-3521219**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

151 Oyster Point Blvd.

Suite 400

South San Francisco, CA 94080

(Address of principal executive offices, including Zip Code)

Registrant s telephone number, including area code: (650) 515-3185

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 (see General Instructions A.2. below):

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 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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 8.01 Other Events

CytomX Therapeutics, Inc., a Delaware corporation (the Company), today announced preliminary clinical results from two arms of the PROCLAIM (PRObody CLinical Assessment In Man) module, PROCLAIM-072. PROCLAIM-072 is an ongoing Phase 1/2 trial evaluating CX-072, a Probody therapeutic targeting PD-L1, as monotherapy and in combination with Yervoy® (ipilimumab) or Zelboraf® (vemurafenib) in patients with advanced, unresectable solid tumors. Data from the CX-072 monotherapy arm and ipilimumab combination arm were presented today in two posters as part of the Developmental Therapeutics Immunotherapy Session at the 2018 Annual Meeting of the American Society of Clinical Oncology in Chicago, Illinois.

Enrollment of Part A1 of PROCLAIM-072, the initial dose escalation stage, was completed in December 2017. The primary objectives of this first-in-human, dose-escalation, monotherapy arm are to assess safety and tolerability, including determination of the maximum tolerated dose (MTD) and the dose-limiting toxicity (DLT) of CX-072 as monotherapy. At the completion of escalation, the arm had enrolled 22 patients, with an average of four prior anti-cancer treatments in a variety of tumor types for which no anti-PD-1 or anti-PD-L1 agents are available for their disease. Patients received escalating doses of CX-072 from 0.03 mg/kg to 30 mg/kg. Patient follow-up is ongoing. The Company presented the following data with respect to Part A1:

Monotherapy Well Tolerated The maximum tolerated dose (MTD) was not reached. As of an April 20, 2018 data cutoff, results showed that the administration of monotherapy CX-072 was well tolerated with the majority of treatment-related adverse events (TRAEs) as Grade 1/2. Grade 3/4 TRAEs were reported in two patients: neutropenia and thrombocytopenia in a patient with thymic cancer (3 mg/kg) and transaminase elevation in a patient with breast cancer (30 mg/kg). Both events were successfully managed with therapeutic intervention including steroids and discontinuation of CX-072.

Evidence of Activity As of an April 20, 2018 data cutoff, results showed that among 20 evaluable patients who received CX-072, objective responses by Response Evaluation Criteria in Solid Tumors (RECIST) version 1.1, a commonly used guideline for evaluating tumors, were observed in three (15%) patients: thymoma (unconfirmed partial response (uPR); three mg/kg), PD-L1 negative TNBC (confirmed PR; 10 mg/kg) and cervical cancer (uPR; 10 mg/kg) (all partial responses (PR)). Stable disease was observed in eight patients (40%) for a disease control rate of 55%. Decreased target lesions were observed in 42% (8/19) of all evaluable patients with measurable disease at baseline and in 60% (6/10) of the subset of patients who received $\geq$ 3 mg/kg of CX-072. Two of the responders were still on treatment (eight months each) at the time of the data cutoff.

Evidence of Probody Platform Performance Results from a preliminary single-dose pharmacokinetic analysis of single-agent CX-072 suggest that, as designed, CX-072 circulates predominantly as the intact masked prodrug across all dose levels. Further, CX-072 is only minimally influenced by target mediated drug disposition at low doses, suggesting that masking is effective in blocking interaction with PD-L1 in the periphery.

Based on these preliminary safety, efficacy and translational data, further evaluation of CX-072 monotherapy (10 mg/kg every two weeks) is now underway in eight expansion cohorts in a variety of cancer types.

The primary objectives of Part B of PROCLAIM-072 are to assess safety and tolerability, and to determine the MTD and DLT of CX-072 when administered in a concomitant combination schedule with ipilimumab. At the April 20, 2018 data cutoff, the study had enrolled 16 immunotherapy naïve patients who had received an average of four prior anti-cancer treatments in a variety of tumor types for which no anti-PD-1 or PD-L1 agents were available for their

disease. Patients received the combination ipilimumab (3 mg/kg) and CX-072 (escalating doses of 0.3 mg/kg to 10 mg/kg) every three weeks for four cycles followed by monotherapy CX-072 every two weeks. The study is still ongoing with enrollment and dose escalation continuing. The Company presented the following data with respect to Part B:

Combination with Ipilimumab Well Tolerated As of the April 20, 2018 data cutoff date, the MTD had not yet been reached and no new safety signals were observed beyond those expected for each component of the ipilimumab plus CX-072 combination. The majority of TRAEs were Grade 1/2. Of the 16 treated patients, five (31%) reported a Grade 3/4 TRAE, a rate similar to that reported previously for 3 mg/kg ipilimumab monotherapy. These events included: Grade 3 colitis (n=1), Grade 3 dyspnea/pneumonitis (n=1), Grade 3 headache/Grade 3 hyponatremia (n=1), and Grade 3 amylase/Grade 4 lipase (n=1). A Grade 3 TRAE in one patient was designated as non-treatment related post data cutoff. A dose limiting toxicity of Grade 3 dyspnea was reported in one patient.

Evidence of Activity As of an April 20, 2018 data cutoff, results also showed that among 12 evaluable patients who received ipilimumab (3 mg/kg) combined with CX-072 (0.3 to 10 mg/kg), three (25%) achieved objective responses by

RECIST v1.1, including patients with: anal cancer (confirmed complete response (CR); 0.3 mg/kg CX-072), testicular cancer (uPR; 1 mg/kg CX-072) and cancer of unknown primary (uPR; 3 mg/kg CX-072). Stable disease was observed in 8% of patients for a disease control rate of 33%. All three of the responders remained on treatment (ten, six and five months, respectively) at the data cutoff.

In addition to the foregoing, preliminary pharmacokinetic clinical data showed that single-agent, single-dose CX-072 behaved as designed and circulated predominantly as the intact antibody prodrug and is only minimally affected by target-mediated drug disposition, consistent with being effectively masked in circulation.

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.

Date: June 4, 2018

CYTOMX THERAPEUTICS, INC.

By:

/s/ Debanjan Ray
Debanjan Ray
Chief Financial Officer