

CytomX Therapeutics, Inc. Logo

CytomX Therapeutics Presents Preliminary Clinical Proof-of-Concept Data from Probod™ Platform and CX-072 at 2018 ASCO Annual Meeting

June 4, 2018 at 9:00 AM EDT

– PD-L1 Targeting Probod CX-072 Well Tolerated and Shows Antitumor Activity as Monotherapy and in Combination with Ipilimumab –
– Company to Host Conference Call and Webcast Today Monday, June 4th at 5:00 p.m. CT / 6:00 p.m. ET –

SOUTH SAN FRANCISCO, Calif., June 04, 2018 (GLOBE NEWSWIRE) -- CytomX Therapeutics, Inc. (Nasdaq:CTMX) a clinical-stage oncology-focused biopharmaceutical company pioneering a novel class of investigational antibody therapeutics based on its Probod™ therapeutic technology platform, today presented 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 Probod 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 (ASCO) in Chicago, Illinois.

“These first clinical results mark a major milestone for CytomX as we advance our Probod platform and introduce a fundamentally new approach to antibody therapeutic drug development,” said Sean McCarthy D.Phil., president and chief executive officer of CytomX Therapeutics. “The findings presented today show that our lead wholly-owned program, the PD-L1 targeting Probod therapeutic, CX-072, has the potential to become a new centerpiece of combination cancer therapy. These preliminary results suggest that CX-072 as monotherapy and in combination with ipilimumab has a favorable safety profile and encouraging antitumor efficacy in late-stage, heavily pretreated cancer patients. Moreover, these clinical data check important boxes for the development of our core platform technology by showing that CX-072 remains stable in circulation over extended periods of dosing and elicits anti-tumor effects within the tumor microenvironment. Based on these initial results, we have initiated multiple monotherapy expansion cohorts to further explore the safety and efficacy of this potentially differentiated PD-L1 inhibitor.”

[Preliminary Results of the First-In-Human, Dose-Finding PROCLAIM-072 Trial of the PD-L1 Probod Therapeutic CX-072 as Monotherapy in Patients with Advanced Solid Tumors](#)

Session: Developmental Therapeutics—Immunotherapy (Poster #285)
Presenter: Karen A. Autio, M.D., MSc., Memorial Sloan Kettering Cancer Center

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. Enrollment is complete and patient follow-up is ongoing.

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 3 (15%) patients: thymoma (unconfirmed PR (uPR); 3 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 8 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 > 3 mg/kg of CX-072. Two of the responders were still on treatment (8 months each) at the time of the data cutoff.

Evidence of Probod 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 8 expansion cohorts in a variety of cancer types.

[Preliminary Interim Results of the First-In-Human, Dose-Finding PROCLAIM-072 Trial of the PD-L1 Probod Therapeutic CX-072 in Combination with Ipilimumab in Patients with Advanced Solid Tumors](#)

Session: Developmental Therapeutics—Immunotherapy (Poster #286)
Presenter: Rachel E. Sanborn, M.D., Earle A. Chiles Research Institute, Providence Cancer Center

The primary objectives of this ongoing arm of the study 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.

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, 5 (31%) reported a Grade 3/4 TRAE, a rate similar to that reported previously for 3 mg/kg ipilimumab monotherapy¹. 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)². A dose limiting toxicity of Grade 3 dyspnea was reported in one patient. The study is still ongoing with enrollment and dose escalation continuing.

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), 3 (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 3 of the responders remained on treatment (10, 6 and 5 months, respectively) at the data cutoff.

[Preliminary Single-Dose Clinical Pharmacokinetics of an anti-PD-L1 Probody Therapeutic in Cancer Patients](#)

ASCO Supplement of the Journal of Clinical Oncology [J Clin Oncol 36, 2018 (suppl; abst 214558)]. (Abstract #e14558)

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.

Conference Call and Webcast

CytomX will host a conference call and live webcast with slides today, Monday, June 4, 2018, beginning at 5:00 p.m. CT/ 6:00 p.m. ET to discuss these data presentations. This event can be accessed in three ways:

- From the CytomX website: <http://ir.cytomx.com/events-and-presentations>. Please access the website 15 minutes prior to the start of the call to download and install any necessary audio software.
- By telephone: Participants can access the call by dialing 1-877-809-6037 (United States) or 1-615-247-0221 (International) referencing Conference ID 4294667.
- By replay: A replay of the webcast will be located under the Investor Relations section of CytomX's website approximately two hours after the conclusion of the live call and will be available for 30 days following the call.

About PROCLAIM

PROCLAIM (Probody Clinical Assessment In Man) is an international umbrella program designed to evaluate CytomX's Probody therapeutics. The first module is the PROCLAIM-CX-072 clinical program, an open-label, dose-finding Phase 1/2 trial evaluating CX-072 as monotherapy and in combination with Yervoy® (ipilimumab) or Zelboraf® (vemurafenib) in patients with metastatic or locally advanced unresectable solid tumors or lymphomas. CytomX aims to achieve three goals as part of the PROCLAIM-072 clinical trial:

- Tolerability: Demonstrate that CX-072 is well tolerated in patients and potentially improves safety, particularly in the combination setting.
- Anti-cancer activity: Demonstrate initial evidence of CX-072's anti-cancer activity as monotherapy and in combination.
- Translational program and Probody platform proof-of-concept: Explore mechanistic aspects of Probody activity in patients as observed in preclinical models.

About CytomX Therapeutics

CytomX Therapeutics is a clinical-stage oncology-focused biopharmaceutical company pioneering a novel class of investigational antibody therapeutics based on its Probody therapeutic technology platform. Probody therapeutics are designed to exploit unique conditions of the tumor microenvironment to more effectively localize antibody binding and activity while limiting activity in healthy tissues. The Company's pipeline includes cancer immunotherapies against clinically-validated targets, such as CX-072, a PD-L1-targeting Probody therapeutic wholly-owned by CytomX, BMS-986249, a CTLA-4-targeting Probody therapeutic partnered with Bristol Myers Squibb, CX-188, a PD-1-targeting Probody therapeutic wholly-owned by CytomX, and first-in-class Probody drug conjugates against high potential targets, such as CX-2009, a CD166-targeting Probody drug conjugate wholly-owned by CytomX and CX-2029, a CD71-targeting Probody drug conjugate partnered with AbbVie, which are considered to be inaccessible to conventional antibody drug conjugates due to their presence on healthy tissue. In addition to its wholly owned programs, CytomX has strategic collaborations with AbbVie, Amgen, Bristol-Myers Squibb Company, and ImmunoGen, Inc. For more information, visit www.cytomx.com or follow us on Twitter.

CytomX Therapeutics Forward-Looking Statements

This press release includes forward-looking statements. Such forward-looking statements involve known and unknown risks, uncertainties and other important factors that are difficult to predict, may be beyond our control, and may cause the actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied in such statements. Accordingly, you should not rely on any of these forward-looking statements, including those relating to the potential safety, benefits and efficacy of CX-072, administered separately or in combination, the Company's ability to develop and advance CX-072 into and successfully complete clinical trials, and the timing of any future clinical trials of CX-072. Risks and uncertainties that contribute to the uncertain nature of the forward-looking statements include: CytomX's product

candidates under its Probody platform, including CX-072, are in the initial stages of clinical development, the process by which preclinical and clinical development could potentially lead to an approved product is long and subject to significant risks and uncertainties; the possibility that the results of early clinical trials may not be predictive of future results; the possibility that CytomX's clinical trials will not be successful; possible regulatory developments in the United States and foreign countries; collaborations with partners may not result in products, and milestone payments and royalties may not be received. Applicable risks and uncertainties include those relating to our preclinical research and development, clinical development, collaborations and other risks identified under the heading "Risk Factors" included in CytomX's Quarterly Report on Form 10-Q filed with the SEC on May 9, 2018. The forward-looking statements contained in this press release are based on information currently available to CytomX and speak only as of the date on which they are made. CytomX does not undertake and specifically disclaims any obligation to update any forward-looking statements, whether as a result of any new information, future events, changed circumstances or otherwise.

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¹ Larkin J, et al. *Combined nivolumab and ipilimumab or monotherapy in untreated melanoma*. N Engl J Med 2015;373: 23–34.

² A Grade 3 TRAE in 1 patient was designated as nontreatment related post data cutoff.



Source: CytomX Therapeutics Inc.