

CytomX Therapeutics, Inc. Logo

CytomX Therapeutics Presents Clinical Data from Probody™ Platform and CX-072 at 2018 ESMO Annual Meeting

October 22, 2018 at 6:45 AM EDT

- Additional Data Supports PD-L1 Targeting Probody CX-072 as Well Tolerated with Antitumor Activity as Monotherapy and in Combination with Ipilimumab -

- Company to Host Conference Call and Webcast Today, Monday, October 22nd at 2:30 p.m. CEST /8:30 a.m. EDT -

SOUTH SAN FRANCISCO, Calif., Oct. 22, 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 Probody™ therapeutic technology platform, today presented clinical results from two arms of the PROCLAIM (**PRO**body **CL**inical **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 at the 2018 Annual Meeting of the European Society of Clinical Oncology (ESMO) in Munich, Germany. The data presented at ESMO were based on an August 3, 2018 data cutoff, reflecting an approximately three-month difference from the data cutoff for the presentations made at the American Society of Clinical Oncology (ASCO) Annual Meeting in June.

"Our data presented today continue to support our thesis that CX-072 has potential to be a new and differentiated combination partner for anti-cancer therapy. CX-072 has demonstrated activity both as monotherapy and in combination with ipilimumab and is generally well tolerated in both regimens," said Sean McCarthy D.Phil., president and chief executive officer of CytomX Therapeutics. "We are advancing monotherapy CX-072 towards registrational studies and continuing to explore the full potential of the CX-072/ipilimumab combination. With the clinical data reported today, and at ASCO, the Probody platform is declaring its potential to deliver multiple opportunities to make a meaningful difference for cancer patients."

[Poster 435 - Preliminary Results of PROCLAIM-072: The First-In-Human, Dose-Finding Trial of PD-L1 Probody Therapeutic CX-072 as Monotherapy in Patients with Advanced Solid Tumors](#)

Presenter: Valentina Boni, M.D., Ph.D., Clinical Researcher, START Madrid and Associate Professor, University CEU San Pablo in Madrid, Spain

The primary objectives of Parts A and A2 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. Patients in Part A received escalating doses of CX-072 from 0.03 mg/kg to 30 mg/kg. Patients in Part A2 received escalating doses of CX-072 from 0.3 mg/kg to 10 mg/kg and had mandatory biopsies of PD-L1 positive solid tumors. At the time of the August 3, 2018 data cutoff, Parts A and A2 had enrolled 46 patients, with 11 patients still receiving treatment. Treatment duration for patients in Part A2 was limited at higher doses. Enrollment in Part A is complete and Part A2 is ongoing with patient follow-up ongoing.

Monotherapy Well Tolerated

The maximum tolerated dose (MTD) was not reached. As of an August 3, 2018 data cutoff, results were consistent with previous analyses. The administration of monotherapy CX-072 was generally well tolerated with the majority of treatment-related adverse events (TRAEs) Grade 1/2. Of the 46 treated patients, 5 (11%) reported Grade 3/4 TRAEs and 3 (7%) reported treatment-related serious adverse events (SAEs). Immune-related adverse events (irAE) were reported in 3 (7%) of patients.

Monotherapy Clinical Activity

As of an August 3, 2018 data cutoff, results showed that among 38 evaluable patients who received CX-072, objective responses by Response Evaluation Criteria in Solid Tumors (RECIST) version 1.1 were observed in 3 (8%) patients, all treated at a dose of > 3 mg/kg: PD-L1 negative triple negative breast cancer (confirmed partial response (cPR); 10 mg/kg), thymic cancer (unconfirmed partial response (uPR); 3 mg/kg), and cervical cancer (uPR; 10 mg/kg). Stable disease was observed in 15 (39%) of patients for an overall disease control rate of 47%. For the 18 patients who received CX-072 ≥3 mg/kg, objective responses were observed in 3/18 (17%) and the disease control rate was 61%. Decreased target lesions were observed in 38% (14/37) of all evaluable patients with measurable disease at baseline and in 59% (10/17) of the subset of patients who received > 3 mg/kg of CX-072.

[Poster 436 - Preliminary Interim Results of the First-In-Human, Dose-Finding PROCLAIM-072 Trial Evaluating the PD-L1 Probody Therapeutic CX-072 in Combination with Ipilimumab in Patients with Advanced Solid Tumors](#)

Presenter: Ruth Plummer, M.D., Northern Institute for Cancer Research, Newcastle University

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 August 3, 2018 data cutoff, the study had enrolled 20 immunotherapy naïve patients who had received an average of 3 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 or greater) 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 August 3, 2018 data cutoff date, the MTD had not yet been reached and was generally well tolerated with no new safety signals observed beyond those expected for each component of the CX-072 plus ipilimumab combination. The full dose of 3 mg/kg of ipilimumab in combination with CX-072 10 mg/kg was well tolerated. The majority of TRAEs were Grade 1/2. Of the 20 treated patients, 4 (20%) 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/Grade 3 pneumonitis (n=1), Grade 3 headache/Grade 3 hyponatremia (n=1), and Grade 3 amylase/Grade 4 lipase (n=1). Grade 3/4 irAEs were reported in

2/20 (10%) patients, 0% (0/11) at doses of >3 mg/kg CX-072 with 3 mg/kg of ipilimumab. The study is still ongoing with enrollment and dose escalation continuing.

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

Ipilimumab Combination Clinical Activity

As of an August 3, 2018 data cutoff, results also showed that among 14 evaluable patients who received ipilimumab (3 mg/kg) combined with CX-072 (0.3 to 10 mg/kg), 3 (21%) achieved objective responses by RECIST v1.1, including patients with: anal cancer (confirmed complete response (cCR); 0.3 mg/kg CX-072), testicular cancer (confirmed partial response (cPR); 1 mg/kg CX-072) and cancer of unknown primary (cPR; 3 mg/kg CX-072). Stable disease was observed in 3 additional patients for a disease control rate of 43%. As of the data cutoff, all 3 of the responders remained on treatment with durations of response of 7.4, 5.3, and 3.2 months, respectively.

Probody Pharmacokinetics

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 with 96% intact at 30 mg/kg. 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.

CX-072 Monotherapy and Ipilimumab Combination Expansion Arms

Based upon the results from the Part A CX-072 monotherapy arm presented at ASCO in June, in the second quarter, the Company began dosing patients in Part D, the expansion arm examining CX-072 as monotherapy at 10 mg/kg in 8 undisclosed tumor types. The Company has the potential to move one or more of these indications into a registrational trial with the goal of advancing towards commercialization. The Company expects initial Part D clinical data in 2019.

The Company is currently dosing patients in the Part B CX-072 combination with ipilimumab arm at 6 mg/kg of ipilimumab. The Company plans to initiate expansion modules with this combination in the first half of 2019 at doses and indications to be determined.

Conference Call and Webcast

CytomX will host a conference call and live webcast with slides today, Monday, October 22, 2018, beginning at 2:30 p.m. CEST/ 8:30 a.m. EDT to discuss these data presentations and review the next steps for the programs. 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 1275596.
- 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, including a PD-L1-targeting Probody therapeutic wholly owned by CytomX (CX-072), a PD-1-targeting Probody therapeutic wholly owned by CytomX (CX-188) and a CTLA-4-targeting Probody therapeutic partnered with Bristol Myers Squibb (BMS-986249). The pipeline also includes first-in-class Probody drug conjugates against high potential targets including a CD166-targeting Probody drug conjugate wholly owned by CytomX (CX-2009), and a CD71-targeting Probody drug conjugate partnered with AbbVie (CX-2029) are among cancer targets that have been considered to be inaccessible to conventional antibody drug conjugates due to their presence on many healthy tissues. CytomX and its partners have four programs in the clinic. 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.

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 August 8, 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.

CytomX Therapeutics

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