CytomX Therapeutics, Inc. Logo

CytomX Therapeutics Announces Initiation of Phase 2 Clinical Trial Evaluating the Anti-PD-L1 Probody CX-072 in Combination with YERVOY® in Patients with Relapsed or Refractory Melanoma

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- Updates Phase 1 PROCLAIM-CX-072-001 Ipilimumab Combination Study Data -

SOUTH SAN FRANCISCO, Calif., Oct. 29, 2019 (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 announced the initiation of the Phase 2 PROCLAIM (**Pr**obody **Cl**inical **A**ssessment **I**n **M**an) CX-072-002 program evaluating the anti-PD-L1 Probody CX-072, in combination with the anti-CTLA-4 antibody, YERVOY® (ipilimumab), in patients with relapsed or refractory melanoma.

“The initiation of this first Phase 2 study for CX-072 marks the ongoing advancement of our innovative pipeline of Probody therapeutics and reflects our vision for this novel checkpoint inhibitor to become a differentiated centerpiece of combination therapies in multiple cancer types,” said Sean McCarthy, D.Phil., president, chief executive officer and chairman of CytomX Therapeutics.

“Patients whose melanoma has progressed despite prior treatment with checkpoint inhibition remain a significant unmet medical need. This exciting study leverages our unique technology platform to enable a more powerful combination therapy directed against the two best validated pathways in immuno-oncology and could represent a significant advance in outcomes for these patients who have few treatment options,” said Amy Peterson, M.D., chief development officer of CytomX Therapeutics.

About the PROCLAIM-CX-072-002 Ipilimumab Combination Study

PROCLAIM-CX-072-002 is an open-label, multi-center Phase 2 clinical study (NCT03993379) that allows for the testing of CX-072 in combination with ipilimumab in patients with unresectable or metastatic melanoma whose disease has progressed or relapsed following treatment with a PD-1/PD-L1 immune checkpoint inhibitor. This study will assess the efficacy and tolerability of a fixed dose of 800 mg of CX-072 every three weeks in combination with ipilimumab at the full labelled combination dose and schedule of 3 mg/kg every three weeks for four cycles. CX-072 therapy will be continued once every two weeks after the completion of the combination phase until disease progression. The primary objective is overall response rate (ORR) as defined by Response Evaluation Criteria in Solid Tumors (RECIST) v1.1 with secondary objectives evaluating the safety and tolerability of CX-072. The cohort utilizes a Simon 2 Stage design with approximately 40 patients being enrolled into Stage 1 with additional patients being enrolled into Stage 2, pending the outcome of Stage 1. CytomX anticipates initial data from Stage 1 in 2020.

Additional information on this trial is available at ClinicalTrials.gov using the identifier NCT03993379.

Unmet Need in Relapsed Refractory Melanoma

Melanoma is a life-threatening form of skin cancer. The incidence of melanoma has been increasing over the last 40 years, with about 150K newly diagnosed patients across major markets in 2018. In the unresectable/metastatic setting, approximately 60% of melanoma patients will receive immune checkpoint blockade (~35% of BRAF+ patients and ~75% of BRAF WT) yet ~85% of those patients will progress. For patients with unresectable/metastatic melanoma who progress after PD-1/L1 therapy, there are limited treatment options available.

Updated Top-Line Results from the Phase 1 PROCLAIM-CX-072-001 Ipilimumab Combination Study

This open-label, dose-finding study evaluated CX-072 in combination with ipilimumab in patients with advanced solid tumors. Preliminary data from this trial was first presented at the American Society of Clinical Oncology (ASCO) 2018 Annual Meeting and enrollment is complete. Updated data, as of an October 2019 snapshot, showed that among 27 evaluable patients who received ipilimumab (3, 6 or 10 mg/kg) combined with CX-072 (0.3, 1, 3 or 10 mg/kg), the disease control rate (stable disease or better) was 37%. Five patients achieved confirmed objective responses by RECIST v1.1 including one complete response, for an ORR of 19% in these heavily pretreated patients. The median duration of response was 14.6 months (1.9 - 21.2 months) with 4 of the 5 responders still on treatment as of the latest data snapshot.

The recommended combination dose for further investigation is 3 mg/kg of ipilimumab and 10 mg/kg of CX-072 (dose equivalent of 800 mg). This combination was generally well tolerated with no new safety signals observed. Of the 27 patients treated across all doses, Grade 3/4 treatment related adverse events (TRAE) were reported in 9 (33%) patients and Grade 3/4 immune related adverse events (irAEs) were reported in 6 (22%) patients. Of the 20 patients treated with ipilimumab at 3 mg/kg at varying doses of CX-072, Grade 3/4 TRAEs were reported in 5 (25%) patients and Grade 3/4 irAEs were reported in 3 (15%) patients.

The Company is preparing data from the Phase 1 PROCLAIM-CX-072-001 study for publication.

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 minimizing activity in healthy tissues. CytomX and its partners have four programs in the clinic. The Company’s clinical stage pipeline includes cancer immunotherapies against clinically validated targets, including a PD-L1-targeting Probody therapeutic wholly owned by CytomX (CX-072) and a CTLA-4-targeting Probody therapeutic partnered with Bristol Myers Squibb (BMS-986249). The CytomX clinical stage pipeline also includes first-in-class Probody drug conjugates against highly attractive 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). CD166 and CD71 are among cancer targets that are considered to be inaccessible to conventional antibody drug conjugates due to their presence on many healthy tissues. 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. In particular, clinical data referenced above for CX-072 including data on efficacy and safety, is based on a limited dataset and a limited number of patients and at specific doses and, in some cases, specific cancer types. Accordingly, you should not rely on any of these forward-looking statements, including those relating to the potential benefits, safety and efficacy of CX-072, administered separately or in combination, the potential benefits or applications of CytomX's Probody platform technology, CytomX's ability to develop and advance product candidates into and successfully complete clinical trials, including the ongoing clinical trials of CX-072 and CX-2009, and the timing of any future clinical trials to be initiated by CytomX or its collaborative partners. Risks and uncertainties that contribute to the uncertain nature of the forward-looking statements include: the unproven nature of CytomX's novel Probody Platform technology; four of CytomX's product candidates under its Probody platform are in the initial stages of clinical development and its other product candidates are currently in preclinical development, and 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; CytomX's dependence on the success of CX-072, CX-2009, CX-2029 and BMS 986249; CytomX's reliance on third parties for the manufacture of the company's product candidates; and possible regulatory developments in the United States and foreign countries. Additional applicable risks and uncertainties include those relating to our preclinical research and development, clinical development, 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 7, 2019. 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.

Contact:

Investors and Media:

Christopher Keenan
VP, Investor Relations and Corporate Communications
ckeenan@cytomx.com
650-383-0823

Source: CytomX Therapeutics Inc.