CytomX Therapeutics, Inc. Logo

CytomX Therapeutics 2019 Research and Development Day Highlights Clinical Data from Lead Programs and the Broad Potential of Probody™ Therapeutic Platform

February 26, 2019 at 7:30 AM EST

- CX-2009, a First-in-Class Probody Drug Conjugate Targeting CD166, Demonstrates Encouraging Anti-Cancer Activity in Multiple Tumor Types and Safety in Phase 1 Dose Escalation -

- CX-072, A Potentially Differentiated Anti-PD-L1 Agent, Shows Favorable Anti-Cancer Activity in Multiple Tumor Types as Monotherapy and in Combination with Yervoy®, with Encouraging Safety Profile that Compares Favorably to Historical Controls for other PD-Pathway Inhibitors -

- Probody Platform Breadth and Versatility Emphasized as Company's Oncology Pipeline Deepens -

- Research and Development Day Hosted Today in New York from 8:00 a.m. – 11:30 a.m. ET, Live Webcast Available -

SOUTH SAN FRANCISCO,, Feb. 26, 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, will provide a comprehensive update to the company's clinical-stage pipeline today at its 2019 Research and Development Day in New York City.

Members of the CytomX management team including Sean McCarthy, D.Phil. president, chief executive officer and chairman; Rachel Humphrey, M.D, chief medical officer and Michael Kavanaugh, M.D., chief scientific officer and head of research and non-clinical development, will lead presentations beginning at 8:00 a.m. EST. Alex Spira, M.D., Ph.D., FACP, Director, Virginia Cancer Specialists Research Institute, Assistant Professor, Johns Hopkins School of Medicine and Medical Director, US Oncology Lung Program will discuss his views on industry trends as well as his experiences as a clinical trial investigator for PROCLAIM-CX-072 and PROCLAIM-CX-2009.

"Our inaugural R&D Day will showcase the tremendous progress CytomX has made in building a pipeline of novel anti-cancer agents with our highly innovative Probody technology platform," said Sean McCarthy, D. Phil, president, chief executive officer and chairman of CytomX Therapeutics. "Several years ago, we set out to reimagine and reinvent therapeutic antibodies so we could make a big difference for cancer patients. The emerging clinical data from our two lead programs support the utility of our Probody technology in achieving this vision and sets us on a path to building the long-term, integrated biotechnology company we have always envisaged."

2019 Research and Development Day Program Highlights

CX-072 Anti-PD-L1 Probody Therapeutic Monotherapy: Continues to Demonstrate Favorable Safety and Durable Anti-Cancer Activity with Encouraging Early Snapshot of Data from Expansion Cohorts in Select Tumor Types at 10 mg/kg:

CX-072 is a wholly owned Probody therapeutic targeting programmed cell death ligand 1 (PD-L1). The Company's PROCLAIM-CX-072 Monotherapy dose escalation (Parts A and A2) trial is complete without a maximum tolerated dose (MTD) having been reached. Of 24 efficacy evaluable patients with generally weakly immunogenic tumors and treated with doses greater than or equal to 3 mg/kg of CX-072, 12 (50%) demonstrated tumor shrinkage including four partial responses; one confirmed partial response (ongoing), 2 unconfirmed partial responses who are off study and one unconfirmed partial response (ongoing with confirmation scan pending). CX-072 as monotherapy was generally well tolerated in the study.

CytomX selected 10 mg/kg as the dose for its expansion cohorts (Part D). This dose was chosen because it was estimated to achieve a greater than 98% receptor occupancy of PD-L1 expressed on the tumor, demonstrated a favorable safety profile, and demonstrated evidence of biological activity. Pharmacokinetic exposure at the 10 mg/kg dose was sustained above the target level regardless of anti-drug antibody (ADA) status (8 of 13 evaluated patients were positive, 4 were negative, and one had unknown status as of December 2018).

Today, the company will present preliminary data from the Company's PROCLAIM-CX-072 Part Devaluating CX-072 at 10 mg/kg in patients with triple negative breast cancer (TNBC), undifferentiated pleomorphic sarcoma (UPS), cutaneous squamous cell carcinoma (cSCC) and anal squamous cell carcinoma (SCC) as of a February 6, 2019 data cutoff. Additional cohort expansions in Merkel cell carcinoma, cancers with high tumor mutational burden (hTMB), thymic cancer and small bowel adenocarcinoma are underway. For the TNBC, UPS, SCC and cSCC cohorts, preliminary data from 34 efficacy evaluable patients, showed a preliminary pattern of anti-cancer activity generally consistent with historical data for other PD inhibitors. Of 50 patients evaluable for safety in the four cancers tested as of the data cutoff date, CX-072 as monotherapy was generally well tolerated, with 2 (4%) patients experiencing a Grade 3/4 treatment-related adverse events (TRAE), 2 (4%) patients experiencing a Grade 3/4 immune-related adverse events (irAE) and no discontinuation for treatment-related toxicity. These data compare favorably to historical controls where the rate of Grade 3/4 TRAEs in patients receiving PD-pathway inhibitors and TRAEs leading to discontinuation are 15% and 8%, respectively. Today's featured speaker, Dr. Spira, will review a case study of a patient from PROCLAIM-CX-072.

CX-072 anti-PD-L1 Probody Therapeutic in Combination with YERVOY® (ipilimumab) Continues to Demonstrate Durable Anti-Cancer Activity and a Favorable Safety Profile:

The Company's PROCLAIM-CX-072 combination dose escalation of CX-072 with ipilimumab (Part B1) is complete with the MTD defined as the combination of 3 mg/kg of ipilimumab and 10 mg/kg of CX-072. Of 19 patients evaluable for efficacy, four (21%) patients experienced confirmed responses as of the February 6, 2019 data cutoff. Three of the four confirmed responses remained on drug as of the data cutoff, including one confirmed complete response (82 weeks) and 2 confirmed partial responses (59 and 64 weeks). Of 27 patients treated with CX-072 in combination with ipilimumab, all with the full ipilimumab dose of 3 mg/kg or above, the combination was generally well tolerated. As of the February 6, 2019 data cutoff, 7 (26%) patients reported a Grade 3/4 TRAE and 3 (11.1%) patients reported a Grade 3/4 irAE. No patients experienced a Grade 3/4 irAE in the 3 mg/kg ipilimumab plus 10 mg/kg of CX-072 arm. These data generally compare favorably with historical controls where the rate of Grade 3/4 treatment-related adverse events in patients receiving a low dose of nivolumab (1 mg/kg) and full dose ipilimumab (3 mg/kg) was reported to be 55%.[1]

CX-2009, a First-In-Class CD166 Targeting Probody Drug Conjugate, Demonstrates Anti-Cancer Activity Across a Range of Doses and Tumor Types and an Encouraging Safety Profile

CX-2009 is a wholly owned Probody drug conjugate (PDC) that targets CD166, an antigen that is broadly and highly expressed in many types of cancer. CX-2009 is conjugated with the DM4 payload, a clinically-validated toxin licensed from ImmunoGen, Inc.

The Company's PROCLAIM-CX-2009 dose escalation trial is complete. Patients with breast, castration-resistant prostate, cholangiocarcinoma, endometrial, head and neck, non-small cell lung and ovarian cancers were enrolled with the study comprised of two parts (Part A - unselected patients; Part A2 – patients selected for high CD166 levels). During dose escalation, 76 patients were treated at doses ranging from 0.25 to 10 mg/kg of CX-2009 every 3 weeks. The MTD was not reached. As of the February 6, 2019 data cutoff date, preliminary data from 46 efficacy evaluable patients demonstrated evidence of anti-cancer activity observed at doses of greater than or equal to 4 mg/kg. Tumor shrinkage was observed in 16 (34.8%) patients in multiple tumor types with 5 unconfirmed partial responses (2 each in ovarian and breast cancers and one in head and neck cancer). Of note, comparable levels of anti-cancer activity was observed in patients who were PD-pathway inhibitor naive or resistant, respectively.

CX-2009 was generally well tolerated in the trial with 23 (30.3%) patients experiencing a Grade 3/4 TRAE. The most common adverse event observed was ocular toxicity, an anticipated toxicity associated with the DM4 payload. Other Grade 3/4 TRAEs included liver function test abnormalities, gastrointestinal disorders and nervous system disorders. Currently, dose optimization is underway to further to inform dose selection. Ocular toxicity prophylaxis has been introduced to this dose optimization phase. Dr. Spira, will also review a case study of a patient from PROCLAIM-CX-2009.

"These preliminary data from our ongoing PROCLAIM program provide additional proof of concept for both CX-072 and CX-2009, as well as the Probody platform itself," said Rachel Humphrey, M.D, chief medical officer of CytomX Therapeutics. "CX-072 continues to behave as designed with a safety profile as monotherapy and in combination that has the potential for meaningful differentiation from other PD-pathway inhibitors, while maintaining the expected efficacy for the class. As additional data emerge from the ongoing clinical program, we will be further defining the utility of this agent in the rapidly evolving oncology landscape."

Continued Dr. Humphrey, "Our CX-2009 data shows the ability of our technology to potentially address an entirely new class of highly expressed tumor antigens, with the opportunity to make otherwise undruggable targets available to patients with a wide variety of cancers."

The Next Wave of Innovation

Dr. Michael Kavanaugh will present an update on the broad potential of the Probody platform across a range of therapeutic antibody formats including Probody Drug Conjugates and the application of Probody technology to the emerging modality of T-Cell engaging Bispecific Antibodies (Probody TCBs). Regarding PDCs, Dr. Kavanaugh will describe the company's strategy for PDC target selection and validation. Regarding Probody TCBs, Dr. Kavanaugh will outline the potential of Probody technology to enable the expansion of the TCB modality to the treatment of solid tumors. Ongoing work aimed at the further optimization of the company's innovative Probody technology platform will also be presented.

Anticipated 2019 Milestones

PROCLAIM-CX-072 (PD-L1 Probody Therapeutic)

- Additional data from monotherapy expansions in selected tumor types at 10 mg/kg arm (Part D).
- Initiation of expansion studies of combination with ipilimumab in selected tumor types.
- Preliminary data from the combination arm with Zelboraf® (vemurafenib) in patients with V600E BRAF-positive melanoma (Part C).

PROCLAIM-CX-2009 (CD166 Probody Drug Conjugate)

- Additional safety and efficacy data from the monotherapy dose escalation arm (Parts A and A2).
- Initiation of an expansion cohort(s) in selected tumor types at a selected dose.

CytomX today announced that due to a recent program and portfolio prioritization, the company has decided to indefinitely postpone the clinical trials of CX-188, a PD-1 Probody. The Company may elect to initiate clinical trials of CX-188 in the future.

Bristol-Myers Squibb (BMS) Collaboration Update

- As part of our strategic oncology collaboration, BMS has advanced BMS-986249, a CTLA-4 Probody therapeutic, into an ongoing Phase 1/2 clinical trial. BMS has stated that they anticipate preliminary data from this trial in 2019.
- In January 2019, BMS provided CytomX notification of termination for three collaboration discovery targets due to portfolio reprioritization. The termination of these targets does not affect other ongoing collaboration discovery and development activities that include BMS-986249.

CytomX 2019 Research and Development Day Webcast

CytomX will host its 2019 Research and Development Day this morning from 8:00 a.m. - 11:30 a.m. ET in New York, NY. The event will be webcast live under the "Investors & News" section of the CytomX website at http://ir.cytomx.com/events-and-presentations. Please connect to the webcast several minutes prior to the start of the broadcast to ensure adequate time for any software download that may be necessary. An archived webcast replay will be available on the Company's website for 90 days following the event.

FY 2018 Financial Results Conference Call and Webcast

CytomX will report full-year 2018 financial results tomorrow, Wednesday, February 27, 2019, after the close of U.S. markets. Following the announcement, the Company will host a conference call beginning at 5:00 p.m. ET to discuss its results. Participants may access the live audio webcast of the teleconference from the "Investors & News" section of CytomX's website. An archived replay of the webcast will be available on CytomX's website until March 6, 2019. The live audio of the conference call can also be accessed by telephone by dialing either (877) 809-6037 (United States and Canada) or (615) 247-0221 (international) and referencing the conference ID 3748238. An archived webcast replay will be available on the Company's website from February 27, 2019, until March 6, 2019.

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. 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 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, data summarized above for CX-072 and CX-2009, including data on efficacy and safety, including treatment related adverse events, immune related adverse events and anti-drug antibodies, is based on 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 CytomX's Probody Platform technology or any of it or its collaborative partners' product candidates, CytomX's expectations regarding the potential applications of its Probody Platform technology, CytomX's expectations regarding the timing and initiation of clinical trials, CytomX's expectations regarding the timing and availability of clinical data from its ongoing clinical trials, and CytomX's ability and the ability of its collaborative partners to develop and advance product candidates into and successfully complete clinical trials, including CytomX's Phase 1/2 clinical trials of CX-072, CX-2009 and CX-2029. 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; three 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 and that additional side effects may be uncovered; the possibility that CytomX's clinical trials will not be successful; CytomX's dependence on the success of CX-072, CX-2009 and CX-2029; 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 Securities and Exchange Commission (SEC) on November 6, 2018 and CytomX's Annual Report on Form 10-K to be filed with the SEC on February 27, 2019, as well as other documents that may be filed by the Company from time to time with the Securities and Exchange Commission. 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. N Engl J Med 2015; 373:23-34 DOI: 10.1056

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