CytomX Therapeutics, Inc. Logo

AACR 2019 Presentations Highlight CX-2009, a First-In-Class Probody Drug Conjugate Targeting Novel Tumor Antigen, CD166

April 2, 2019

- PROCLAIM-CX-2009 Dose Escalation Study Demonstrates Anti-Tumor Activity in Multiple Tumor Types -

- Preclinical Studies Suggest Role of CD166 Expression Level in Anti-Cancer Activity and Potential for Combination of CX-2009 with Immunotherapy -

SOUTH SAN FRANCISCO, Calif., April 02, 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 presentation of clinical and preclinical data for CX-2009, a CD166 targeting Probody Drug Conjugate (PDC), at the 2019 American Association for Cancer Research (AACR) Annual Meeting in Atlanta, Georgia.

“Collectively, these data highlight the potential opportunity for CX-2009, a novel first-in-class CD166-targeting anti-cancer agent,” said Sean McCarthy, D. Phil., president, chief executive officer and chairman of CytomX. “In our first clinical dose escalation with CX-2009, we have seen clear evidence of tumor shrinkage in multiple cancers in heavily pretreated patients and an encouraging safety profile. The safety profile of CX-2009 is of particular note given the widespread expression of CD166 on normal tissues and suggests that CytomX masking technology can allow targeting of novel, broadly distributed antigens. Moreover, our preclinical and clinical research is revealing a relationship between target levels and anti-cancer activity, further validating CD166 as a potential new point of intervention in cancer treatment. In addition, our preclinical research into the combination of CX-2009 with a PD-1 Probody provides preliminary evidence for the potential of these two mechanisms to synergize with each other. Based on these integrated observations presented at AACR 2019, we are excited to advance CX-2009 to the next phase of development.”

Preliminary Results of PROCLAIM-CX-2009, a First-in-Human, Dose-Finding Study of the Probody™ Drug Conjugate CX-2009 in Patients with Advanced Solid Tumors

Presenter: Funda Meric-Bernstam. M.D., Chair of the Department of Investigational Cancer Therapeutics, Medical Director of the Institute for Personalized Cancer Therapy, and Professor, Divisions of Cancer Medicine and Surgery, MD Anderson Cancer Center

Preliminary safety and antitumor activity were reported from the dose-escalation phase (Part A and A2) of the ongoing PROCLAIM-CX-2009 study evaluating CX-2009 in seven selected tumor types. As of a February 26, 2019 data snapshot, 78 patients were enrolled. Of 71 patients evaluable for efficacy, for patients who received ≥4 mg/kg of CX-2009 and had at least one post-baseline on-study tumor assessment, 15/39 (38%) achieved tumor shrinkage, including seven unconfirmed partial responses (4 patients with breast cancer, 2 with ovarian cancer and one with head and neck cancer). 29/39 (74%) achieved stable disease or better at the time of the first on-treatment scan.

CX-2009 was generally well tolerated. The maximum tolerated dose (MTD) was not reached at the highest dose level tested of 10 mg/kg. The most common treatment-related adverse events (TRAE) were grade 1 and 2 and included nausea (32%), fatigue (24%) and decreased appetite (23%). The most common grade 3/4 TRAE was keratitis (8%).

A Probody™ Drug Conjugate Targeting CD166 (ALCAM) Enhances Preclinical Antitumor Activity of a Probody Therapeutic Targeting PD-1

Presenter: Erwan Le Scolan, Ph.D., Senior Scientist, CytomX Therapeutics

The anti-tumor activity of CX-2009 was studied in a syngeneic mouse model. Results show that the combination treatment of CX-2009 with a surrogate mouse anti-PD-1 Probody significantly inhibited tumor growth in mouse CT-26 tumors engineered to express human CD166, as compared to either agent as a monotherapy. In addition, CX-2009 was shown to induce immunogenic cell death of cancer cells in vitro while sparing T cells, an action that may enhance T cell priming. These results highlight the potential to combine the PDC CX-2009 with a Probody therapeutic targeting the PD pathway, such as the CytomX anti-PD-L1 Probody, CX-072, as well as potentially combining other antibody drug conjugates or PDCs with immune checkpoint inhibitors.

CD166-DM4 Probody™ Drug Conjugate (CX-2009) Treatment of 198 Patient-derived Xenograft Models (PDX) in a Mouse Clinical Trial Format

Presenter: Bob Liu, Ph.D., Senior Scientist, CytomX Therapeutics

CytomX is evaluating the anti-tumor activity of CX-2009 in 198 PDX tumor models in a mouse clinical trial format dosed with 5 mg/kg of CX-2009 every 2 weeks for 3 doses. 129 models (65%) had been dosed at the time of data cutoff. Results from the ongoing study show anti-tumor activity in 82% of the models compared to control. Tumor shrinkage relative to pre-dosing was observed in 22% of models relative to untreated controls, and 48% of CX-2009-treated tumors yielded tumor growth inhibition of greater than 50%. CD166 mRNA level was associated with antitumor activity, which may provide a strategy for prospectively identifying patients most likely to respond to CX-2009.

About CX-2009 and the PROCLAIM-CX-2009 Trial

CX-2009, a PDC that targets the cell surface protein CD166, is being developed for the treatment of solid tumors. CD166 is highly and homogeneously expressed on multiple tumor types. CX-2009 is designed to target CD166 specifically in the tumor microenvironment and deliver the tubulin-destabilizing maytansine payload, DM4, to cancer cells. In preclinical studies, CD166 has been shown to effectively internalize antibody-drug conjugates resulting in potent cell killing in-vitro. CX-2009 has shown anti-cancer activity in multiple preclinical models. CX-2009 is wholly owned by CytomX. The DM4 payload is being developed under license from ImmunoGen Inc.

CX-2009 is being studied within PROCLAIM (**PRO**body **CL**inical **A**ssessment **I**n **M**an), CytomX’s international modular umbrella clinical trial program that encompasses the Phase 1/2 development of multiple Probody therapeutics. PROCLAIM-CX-2009 is a dose-finding Phase 1/2 study evaluating CX-2009 as monotherapy in patients with select cancer types, including non-small cell lung cancer, breast cancer, ovarian cancer, endometrial cancer, cholangiocarcinoma (bile duct cancer), head and neck cancer and castration-resistant prostate cancer. The objectives of the study are to establish the safety, tolerability, pharmacokinetics, pharmacodynamics and preliminary antitumor activity of CX-2009.

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 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 and preclinical data referenced above for CX-2009, including data on efficacy and safety, including treatment related adverse events, is based on a limited dataset, including for the clinical data, the 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 product candidates, administered separately or in combination, the potential benefits or applications of CytomX's Probody platform technology, and CytomX's ability to develop and advance product candidates into and successfully complete clinical trials, including the ongoing clinical trial of CX-2009. 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 Annual Report on Form 10-K filed with the SEC on February 27, 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.

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