CytomX Therapeutics, Inc. Logo

CytomX Therapeutics Announces Publication of First-in-Human Data for CX-2029 in Clinical Cancer Research

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CX-2029 is the first CD71-targeting antibody-drug conjugate (ADC) administrated to patients, with a generally well-tolerated safety profile at doses that elicit anti-tumor responses

SOUTH SAN FRANCISCO, Calif., June 21, 2021 (GLOBE NEWSWIRE) -- CytomX Therapeutics, Inc. (Nasdaq: CTMX), a clinical-stage oncology-focused biopharmaceutical company pioneering a novel class of investigational conditionally activated therapeutics based on its Probody® technology platform, today announced that results from its Phase 1 first-in-human study of CX-2029 in patients with advanced solid tumors were published online in the peer-reviewed journal *Clinical Cancer Research*. This study showed that CX-2029, currently being co-developed by CytomX and AbbVie, was generally well-tolerated and can elicit anti-tumor responses in certain patients.

"These results highlight that our industry-leading Probody platform can be successfully leveraged to create conditionally activated ADCs against previously undruggable targets. For the first time, CD71 has been shown to be a viable therapeutic cancer target," said Alison L. Hannah, M.D., senior vice president and chief medical officer of CytomX Therapeutics.

CD71 is a cell surface protein essential for iron uptake in dividing cells and is highly expressed in a number of solid and hematologic cancers. However, given its central role in iron metabolism, CD71 is present on most healthy cells and has been, until now, undruggable with conventional ADCs. CX-2029 is designed to be activated in the tumor microenvironment by tumor-associated proteases, thereby limiting off-tumor toxicity and creating a therapeutic window for CD71.

The goal of this Phase 1 dose-escalation, multicenter study was to evaluate the safety, pharmacokinetics, pharmacodynamics, and antitumor activity of CX-2029. A total of 45 patients were enrolled to receive CX-2029 intravenously every three weeks at dose levels ranging from 0.1 mg/kg to 5 mg/kg.

Encouraging preliminary clinical activity was observed at doses of 2 mg/kg and higher. Notably, three of four patients with squamous non-small cell lung carcinoma (NSCLC) had stable disease (SD) or better, including two confirmed partial responses (PRs) (at doses of 3 and 5 mg/kg); and seven of eight patients with head and neck squamous cell carcinoma (HNSCC) had SD or better, including one confirmed PR at 3 mg/kg and one prolonged SD ongoing at approximately 25 weeks, as of the reported August 2020 data cutoff.

Despite having received a median of three prior lines of cancer regimens (range, 1–16), these heavily-pretreated patients generally tolerated CX-2029 well. The most common dose-dependent adverse events were anemia and neutropenia, toxicities commonly associated with the payload of this ADC (monomethyl auristatin E). Based on several safety parameters, including no cycle 1 DLTs, no discontinuations due to toxicity, and a long-term tolerability that appeared to be acceptable for chronic administration with supportive care for anemia, 3 mg/kg every 3 weeks was declared the recommended Phase 2 dose.

The ongoing Phase 2 expansion study is evaluating CX-2029 as monotherapy in four cohorts: squamous NSCLC, HNSCC, esophageal and gastroesophageal junction cancers (both adenocarcinoma and squamous histologies), and diffuse large B-cell lymphoma. Initial results are expected in the fourth quarter of 2021.

About CytomX Therapeutics
CytomX is a clinical-stage, oncology-focused biopharmaceutical company with a vision of transforming lives with safer, more effective therapies. We are developing a novel class of investigational conditionally activated therapeutics, based on our Probody® technology platform, for the treatment of cancer. CytomX has strategic drug discovery and development collaborations with AbbVie, Amgen, Astellas, and Bristol Myers Squibb.

Probody therapeutics are conditionally activated biologics designed to remain inactive until they are activated by proteases in the tumor microenvironment. As a result, Probody therapeutics are intended to bind selectively to tumors and decrease binding to healthy tissue, to minimize toxicity and potentially create safer, more effective therapies. As leaders in the field, our innovative technology is designed to turn previously undruggable targets into druggable targets and to enable more effective combination therapies. CytomX and its partners, comprised of leading biotechnology and pharmaceutical companies, have developed a robust pipeline of potential first-in-class therapeutic candidates against novel, difficult to drug targets and potential best-in-class immunotherapeutic candidates against clinically validated targets. The CytomX clinical-stage pipeline comprises five assets, four of which are in Phase 2 clinical studies. First-in-class product candidates against previously undruggable targets include a CD166-targeting conditionally activated antibody-drug conjugate wholly owned by CytomX (praluzatamab ravtansine, CX-2009) and a CD71-targeting conditionally activated antibody-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. The CytomX clinical-stage pipeline also includes cancer immunotherapeutic candidates against validated targets such as the CTLA-4-targeting Probodies, BMS-986249 and BMS-986288, partnered with Bristol Myers Squibb, and our wholly-owned conditionally activated anti-PD-L1 antibody, pacmilimab (CX-072). For additional information about CytomX Therapeutics, visit www.cytomx.com and follow us on LinkedIn and 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 benefits, safety and efficacy or progress of CytomX's or any of its collaborative partners' product candidates, including praluzatamab ravtansine (CX-2009), CX-2029, BMS-986249, BMS-986288, and pacmilimab (CX-072), 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 and planned clinical trials of praluzatamab ravtansine, CX-2029, BMS-986249, BMS-986288, and pacmilimab (CX-072), and the timing of the commencement of clinical trials and other development milestones. 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; CytomX's clinical trial product candidates 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, including the risk that the COVID-19 worldwide pandemic may continue to negatively impact the business, research and clinical operations of CytomX or its partners, including the development of preclinical drug candidates due to delays in and disruption of research activities and the development of clinical drug candidates due to delays in or disruption of clinical trials, including impacts on the enrollment of patients in clinical trials or other clinical trial disruptions; the possibility that the results of early clinical trials may not be predictive of future results, including clinical trials for CX-2029; the possibility that CytomX's clinical trials will not be successful; the possibility that current preclinical research may not result in additional product candidates; CytomX's dependence on the success of praluzatamab ravtansine, CX-2029, BMS-986249, BMS-986288, and pacmilimab (CX-072); 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 May 6, 2021. 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 Contact:
Chau Cheng, PhD MBA
VP, Investor Relations & Corp. Communications
ccheng@cytomx.com
Direct: (650) 273-4999

Investor and Media Contact:
Stern Investor Relations
Stephanie Ascher
stephanie.ascher@sternir.com
212-362-1200

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