CytomX Therapeutics, Inc. Logo

CytomX Therapeutics Announces Positive Initial Phase 1a Dose Escalation Data for Monotherapy CX-904 (EGFRxCD3 PROBODY® T-Cell Engager)

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- CX-904 demonstrated a favorable safety profile with no cytokine release syndrome (CRS) of any grade observed in step-dosing cohorts and no grade >1 CRS observed overall -

- Encouraging initial signs of efficacy observed for CX-904 in advanced pancreatic cancer, including 2 of 6 patients (33%) with a confirmed partial response and all 6 patients (100%) with disease control -

- Preliminary pharmacokinetic and pharmacodynamic analyses are supportive of PROBODY® T-Cell Engager platform mechanism of action -

- Dose escalation and optimization continue -

- Management to hold conference call today at 5 p.m. EDT / 2 p.m. PDT -

SOUTH SAN FRANCISCO, Calif., May 08, 2024 (GLOBE NEWSWIRE) -- CytomX Therapeutics, Inc. (Nasdaq: CTMX), a leader in the field of masked, conditionally activated biologic therapeutics, today announced positive initial data from the ongoing CX-904 Phase 1a dose escalation clinical study, demonstrating a favorable safety profile and confirmed anti-cancer activity. CX-904 is an investigational, masked, conditionally activated PROBODY T-cell engager designed to target the epidermal growth factor receptor (EGFR) on cancer cells and the CD3 receptor on T cells within the tumor microenvironment.

"We are delighted to share these initial results today for CX-904, a highly innovative masked T-cell engager that embodies our vision at CytomX of transforming lives with safer, more effective therapies," said Sean McCarthy, D.Phil., chief executive officer and chairman of CytomX. "These data build on more than a decade of innovation at CytomX, and, we believe, open broad new possibilities for T-cell engagers across many targets and cancer types. For EGFR specifically, a target that is present on normal epithelial tissues, we are very encouraged to see CX-904 working as designed by eliciting meaningful tumor reductions in a very difficult to treat tumor type and with a favorable overall safety profile. We look forward to continuing to explore the potential of this exciting agent in multiple EGFR positive cancers and to determining longer term strategy with our global development partner, Amgen."

As of the April 16, 2024 data cutoff, the Phase 1 study had enrolled 35 patients with advanced metastatic solid tumor types that are generally known to express EGFR, including pancreatic, colorectal (CRC), non-small cell lung cancer (NSCLC), head and neck squamous cell carcinoma (HNSCC), gastric, and esophageal cancers. Patients enrolled in the study were heavily pre-treated and had a median of 4 prior lines of therapy. As of the data cutoff, 19 patients were enrolled into initial non-step dosing cohorts with target doses ranging from 0.007 mg to 6 mg, and 16 patients were subsequently enrolled into step-dosing cohorts with target doses ranging from 5 mg to 10 mg and with tocilizumab prophylaxis. Enrollment into a cohort with a target dose of 15 mg is ongoing.

As of the cutoff date, CX-904 demonstrated a favorable safety profile that supports administration and monitoring of enrolled patients in an outpatient setting.[1] There were no observed cases of CRS of any grade in step-dosing cohorts to-date. In non-step dosing cohorts, only Grade 1 CRS was observed in patients treated at the highest dose of 6 mg. Among all treated patients, the most common treatment-related adverse events (TRAEs) were rash, arthralgia, arthritis, pruritis, and vomiting, the majority of which were low grade, being observed in 14 (40%), 13 (37%), 5 (14%), 5 (14%) and 5 (14%) patients, respectively. Grade 3 TRAEs were tenosynovitis (n=1), arthralgia (n=2), arthritis (n=1), and rash (n=1).

Eight patients had measurable tumor reduction at data cutoff, including 2 of 6 efficacy-evaluable patients (33%) with pancreatic cancer with confirmed partial responses per RECIST 1.1. All 6 efficacy-evaluable patients with pancreatic cancer achieved disease control (objective response or stable disease). For the two patients with a confirmed partial response, one patient (6 mg target dose) achieved an 83% tumor reduction. The second patient (5 mg target dose) with a confirmed response achieved a 51% tumor reduction and remained on study treatment as of the data cutoff. In addition, a third pancreatic cancer patient maintained stable disease with no evidence of tumor growth through 3.5 months of study treatment and remained on treatment as of the data cutoff.

Preliminary pharmacokinetic and pharmacodynamic data were consistent with the PROBODY TCE mechanism of action, including maintained masking in circulation, and CD8+ T-cell margination and tumor infiltration.

CX-904 Phase 1a dose escalation and optimization continue, with future enrollment focused on determining a recommended Phase 2 dose, or doses. The Company expects to provide an additional Phase 1a dose escalation update by the end of 2024. These additional data will inform discussions with CytomX partner, Amgen, towards initiation of Phase 1b expansion cohorts in specific EGFR positive tumor types.

Conference Call & Webcast
CytomX management will host a conference call and simultaneous webcast today at 5 p.m. EDT (2 p.m. PDT) to discuss the first quarter 2024 results and provide an initial CX-904 Phase 1a clinical data update. Participants may access the live webcast of the conference call from the Events and Presentations page of CytomX's website at https://ir.cytomx.com/events-and-presentations. Participants may register for the conference call here and are advised to do so at least 10 minutes prior to joining the call. An archived replay of the webcast will be available on the company's website for at least 30 days.

About CytomX Therapeutics
CytomX is a clinical-stage, oncology-focused biopharmaceutical company focused on developing novel conditionally activated, masked biologics designed to be localized to the tumor microenvironment. By pioneering a novel pipeline of localized biologics, powered by its PROBODY® therapeutic platform, CytomX's vision is to create safer, more effective therapies for the treatment of cancer. CytomX's robust and differentiated pipeline comprises therapeutic candidates across multiple treatment modalities including antibody-drug conjugates ("ADCs"), T-cell engagers, and immune modulators such as cytokines. CytomX's clinical-stage pipeline includes CX-904, CX-2051 and CX-801. CX-904 is a masked, conditionally activated T-cell-

engaging bispecific antibody targeting the epidermal growth factor receptor (EGFR) on tumor cells and the CD3 receptor on T cells. CX-904 is partnered with Amgen in a global co-development alliance. CX-2051 is a masked, conditionally activated ADC directed toward epithelial cell adhesion molecule, EpCAM, with potential applicability across multiple EpCAM-expressing epithelial cancers. CX-2051 was discovered in collaboration with Immunogen, now part of AbbVie. CX-801 is a masked interferon alpha-2b PROBODY® cytokine with broad potential applicability in traditionally immuno-oncology sensitive as well as insensitive (cold) tumors. CytomX has established strategic collaborations with multiple leaders in oncology, including Amgen, Astellas, Bristol Myers Squibb, Regeneron and Moderna. For more information about CytomX and how it is working to make conditionally activated treatments the new standard-of-care in the fight against cancer, visit **www.cytomx.com** and follow us on **LinkedIn** and **X (formerly 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, including those related to the future potential of partnerships or collaboration agreements. 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 CX-904, CX-2051, and CX-801, the potential benefits or applications of CytomX's PROBODY ® therapeutic platform, CytomX's or its collaborative partners' ability to develop and advance product candidates into and successfully complete clinical trials, including the ongoing and planned clinical trials of CX-904, and the timing of the commencement of clinical trials or initial and ongoing data availability for CX-801 and CX-2051, 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® therapeutic 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 possibility that the results of preclinical research and early clinical trials, including initial CX-904 results, may not be predictive of future results; 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 CX-904, CX-801, and CX-2051; CytomX's reliance on third parties for the manufacture of the Company's product candidates; possible regulatory developments in the United States and foreign countries; and the risk that we may incur higher costs than expected for research and development or unexpected costs and expenses. 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 8, 2024. 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.

PROBODY is a U.S. registered trademark of CytomX Therapeutics, Inc.

Company Contact:
Chris Ogden
SVP, Finance and Accounting
cogden@cytomx.com

Investor Contact:
Stern Investor Relations
Stephanie Ascher
stephanie.ascher@sternir.com

Media Contact:
Redhouse Communications
Teri Dahlman
teri@redhousecomms.com

[1] Inpatient monitoring is not required following treatment at cleared dose levels.

Source: CytomX Therapeutics Inc.