CytomX Therapeutics, Inc. Logo

CytomX Announces Positive Interim Data From Phase 1 Dose Escalation Study of EpCAM Antibody Drug Conjugate (CX-2051) Candidate in Patients with Advanced Colorectal Cancer (CRC)

May 12, 2025 at 6:15 AM EDT

- 28% confirmed response rate (5/18) per RECIST v1.1 in unselected patients across doses prioritized for expansion (7.2, 8.6 and 10 mg/kg Q3W) -

- 3 of 7 evaluable patients (43%) with confirmed responses at upper expansion dose (10 mg/kg Q3W) -

- Median progression free survival of 5.8 months as of April 7th 2025 data cutoff -

- Encouraging initial safety profile with no dose limiting toxicities at data cutoff -

- Planning Phase 2 study initiation in 1H 2026 -

- Conference call on Monday, May 12 at 8:00 a.m. ET -

SOUTH SAN FRANCISCO, Calif., May 12, 2025 (GLOBE NEWSWIRE) -- CytomX Therapeutics, Inc. (Nasdaq: CTMX), a leader in the field of masked, conditionally activated biologics, today announced positive interim Phase 1 data for its EpCAM PROBODY® ADC candidate, CX-2051, in advanced, late-line CRC. The data are as of an April 7th 2025 data cutoff from the ongoing CTMX-2051-101 Phase 1 study.

“EpCAM is a high potential and broadly expressed cancer target that has been challenging to drug historically due to expression on normal tissues. We believe we have broken important new ground with our data announced today, which show potential for markedly improved outcomes for CRC patients,” said Sean McCarthy, D. Phil, chief executive officer and chairman of CytomX. “CX-2051 is showing impressive, durable anti-tumor activity in late line metastatic CRC, an area of high unmet need and a very difficult tumor to treat. Furthermore, CX-2051 has been generally well tolerated, highlighting the power of CytomX PROBODY® masking technology.”

Dr. McCarthy added, “Importantly, we believe these results validate EpCAM as an oncology target and unlock a broad development opportunity for CX-2051 in CRC and potentially many other cancer types where EpCAM is expressed. We are excited to rapidly advance CX-2051 for the benefit of CRC patients and to explore the full potential of this novel ADC.”

CX-2051 Phase 1a Interim Data Summary in Advanced, Late-line Colorectal Cancer

- The CTMX-2051-101 study was initiated in April 2024 with dose escalation proceeding through seven dose levels as of April 2025.
- 25 advanced metastatic CRC patients were treated with CX-2051 across dose levels 1 through 5 as of the April 7, 2025 data cutoff. CX-2051 was administered on a once every three week schedule (Q3W).
- The 2.4 mg/kg and 4.8 mg/kg doses were single patient dose escalation cohorts not anticipated to be therapeutically active.
- At the 7.2 mg/kg, 8.6 mg/kg, and 10 mg/kg doses, 23 patients were treated in total, 18 of whom were efficacy evaluable, having had at least one post-baseline tumor assessment as of the data cutoff.

Patient Characteristics:

- The 25 patients enrolled in the study across dose levels 1 through 5 had previously received a median of 4 prior lines of therapy and all patients had previously been treated with irinotecan. 64% of patients had liver metastases, 64% had KRAS mutations, and 96% were microsatellite stable.
- Patients were not preselected based on EpCAM expression levels.

Efficacy Results:
As of the data cutoff, 18 patients were efficacy-evaluable at the expansion doses of 7.2 mg/kg, 8.6 mg/kg, and 10 mg/kg Q3W.

- **Overall response rate (ORR):**
  - 28% of patients (5/18) achieved confirmed partial RECIST v. 1.1 responses. Overall response rates for currently approved therapies in 3rd line or later CRC are in the low to mid-single digit percentages[1].
  - At the 10 mg/kg dose, 3 of 7 evaluable patients (43%) achieved confirmed partial responses.
  - The Disease Control Rate[2] was 94% across the three dose groups (17/18).
- **Durability:**
  - Median progression free survival was 5.8 months as of the data cutoff.
  - 10 of 18 patients remained on study treatment as of the data of cutoff.

Safety Results:
As of the data cutoff, 25 patients were evaluable for safety.

- CX-2051 was generally well-tolerated with manageable adverse events, with no observed dose limiting toxicities. Most

treatment related adverse events (TRAEs) were Grade 1 or Grade 2 in severity.

- The most common reported TRAEs were diarrhea (18 patients, 5 Grade 3), nausea (11 patients, 1 Grade 3), vomiting (8 patients, No Grade 3), fatigue (8 patients, 1 Grade 3), anemia (5 patients, 3 Grade 3), hypokalemia (3 patients, 1 Grade 3), neutrophil count decrease (2 patients, 2 Grade 3) and neutropenia (2 patients, 1 Grade 3). TRAEs included serious adverse events in 5 patients (1 Grade 2, 4 Grade 3). No Grade 4 or 5 TRAEs were observed.
- No events of pancreatitis, interstitial lung disease or febrile neutropenia were reported at time of data cutoff.

CX-2051 Phase 1 Dose Expansions Initiated:

- Dose expansions have been initiated at doses of 7.2 mg/kg, 8.6 mg/kg and 10 mg/kg Q3W.
- A total of 20 patients are expected to be enrolled at each dose level to inform the selection of recommended phase 2 dose.

CX-2051 Anticipated Milestones:

- **CX-2051 Monotherapy for Advanced Late-Line CRC:**
  - Additional Phase 1 data update by Q1 2026
  - Planning Phase 2 study initiation in 1H 2026
- **CX-2051 CRC Combinations:**
  - Potential to initiate CX-2051 combination studies in earlier lines of CRC in 2026
- **CX-2051 Pan-tumor Potential:**
  - Evaluate non-CRC, EpCAM-expressing tumor indications for potential Phase 1b study initiation in 2026

CytomX Investor Event Information

Additional details will be provided on the Company's Investor Call on May 12, 2025 at 8 a.m. EST. 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 CTMX-2051-101 Study

Additional information about the CTMX-2051-101 study can be found here on clinicaltrials.gov.

About CX-2051 (EpCAM PROBODY® ADC)

CX-2051 is an investigational masked, conditionally activated ADC directed toward epithelial cell adhesion molecule (EpCAM) and armed with a topoisomerase-1 inhibitor payload. CX-2051 has potential applicability across multiple EpCAM-expressing epithelial cancers, including CRC, and was discovered in collaboration with ImmunoGen, now part of AbbVie. EpCAM (Epithelial Cell Adhesion Molecule) is a highly expressed but previously undruggable tumor antigen due to expression on normal tissues. CX-2051 is designed to open a therapeutic window for this high potential target and to deliver meaningful anti-cancer activity in solid tumors, including CRC.

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-2051 and CX-801. CX-2051 is a masked, conditionally activated ADC directed toward epithelial cell adhesion molecule (EpCAM), armed with a topoisomerase-1 inhibitor payload. CX-2051 has potential applicability across multiple EpCAM-expressing epithelial cancers, including CRC. 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 CX-2051. 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-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-2051 and CX-801 and the timing of initial and ongoing data availability for our clinical trials, including CX-2051 and CX-801, 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; uncertainties around the Company's ability to raise sufficient funds to carry out its planned research and development; 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-2051 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-2051 and CX-801; 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, including China and the European Union; and the risk that we may incur higher costs than expected for research and development or unexpected costs and expenses or may not obtain expected savings from our announced restructuring. 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 12, 2025. 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] Lonsurf®, Fruzaqla®, Stivarga® package inserts
[2] Disease Control Rate: Patients achieving a best response of stable disease, partial response, or complete response.

Source: CytomX Therapeutics Inc.