CytomX Therapeutics, Inc. Logo

CytomX's Varsetatug Masetecan (EpCAM PROBODY® ADC) Continues to Demonstrate Positive Data Supporting Potential as a New Treatment Option in Late-Line Colorectal Cancer

March 16, 2026 at 7:00 AM EDT

- Confirmed response rates in expansion cohorts of 32% at 10 mg/kg Q3W dose and 20% at 8.6 mg/kg Q3W -

- Estimated progression free survival of 7.1 months at 10 mg/kg and 6.8 months at 8.6 mg/kg -

- Grade 3 diarrhea rate of 10% in ongoing dose optimization cohorts -

- FDA interactions targeted for mid-year with goal to align on potential registrational trial design in late-line colorectal cancer (CRC) -

- Phase 1 study evaluating combination with bevacizumab initiated; Phase 1b/2 chemotherapy combination study to be initiated by the end of 2026 -

- Conference call on Monday, March 16 at 8:00 a.m. ET -

SOUTH SAN FRANCISCO, Calif., March 16, 2026 (GLOBE NEWSWIRE) -- CytomX Therapeutics, Inc. (Nasdaq: CTMX), a leader in the field of masked, conditionally activated biologics, today announced positive Phase 1 expansion data for its EpCAM PROBODY® ADC, varsetatug masetecan (Varseta-M) in late-line metastatic CRC. The preliminary data are as of a January 16, 2026 data cutoff from the ongoing CTMX-2051-101 Phase 1 study.

"These latest Phase 1 data reinforce the potential of Varseta-M to meaningfully improve the standard of care in late-line colorectal cancer. We are now planning interactions with the FDA to discuss the initial registrational path for bringing this highly innovative, first-in-class ADC to the market in late-line CRC," said Sean McCarthy, D. Phil, chief executive officer and chairman of CytomX.

McCarthy added, "Our ultimate vision is to reach a broad CRC patient population with Varseta-M, including in earlier lines of treatment, as well as to expand into additional EpCAM-expressing cancers. We aim to aggressively advance this novel therapy towards late-stage development for the benefit of patients as we set our sights on building CytomX into a commercial-stage company."

"Patients with late-stage metastatic CRC face a poor prognosis and have very limited treatment options. These exciting clinical data demonstrate that Varseta-M can drive consistent and durable responses with a manageable tolerability profile in patients with heavily pretreated CRC, supporting its promise as a potential new treatment option for advanced CRC," said Dr. Kimmie Ng, Associate Chief of the Division of Gastrointestinal Oncology at Dana-Farber Cancer Institute.

Varsetatug Masetecan Phase 1 Expansion 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 ranging from 2.4 mg/kg to 12 mg/kg. As of the data cutoff of January 16th 2026, a total of 93 patients with late-line metastatic CRC had been enrolled in the study. 60 patients were enrolled across the Phase 1 expansion dose range of 7.2 mg/kg, 8.6 mg/kg, and 10 mg/kg of which 56 were efficacy evaluable as of the data cutoff.
- Starting in October 2025, the expansion doses of 8.6 mg/kg and 10 mg/kg were prioritized for dose optimization utilizing optimized adverse event management guidelines and adjusted ideal body weight (AIBW) dosing. 20 patients had been enrolled in expanded dose optimization as of the January 16th data cutoff towards an enrollment goal of 40 patients.

Patient Characteristics:

- Patients enrolled in the study had previously received a median of 3 prior lines of therapy in the metastatic setting and 96% of patients had previously been treated with irinotecan. 76% of patients had liver metastases and 71% had KRAS mutations.
- Patients were not preselected based on EpCAM expression levels. All patients with evaluable tumor biopsies had high EpCAM levels as measured by immunohistochemistry.[1]

Efficacy:

As of the data cutoff, 56 patients were efficacy-evaluable at the expansion doses of 7.2 mg/kg, 8.6 mg/kg, and 10 mg/kg Q3W. Median duration of follow-up across the efficacy-evaluable patient population was approximately 8 months. Efficacy data across the Phase 1 Expansion doses are summarized below in Table 1.

Table 1. Varseta-M Efficacy Summary by Phase 1 Expansion Dose

	7.2 mg/kg	**8.6 mg/kg**	**10 mg/kg**
Confirmed Overall Response Rate (ORR)[2]	6% (1/17)	20% (4/20)	32% (6/19)

Median Progression Free Survival (PFS)	5.5 mo. (95% CI: 2.5, NE)	6.8 mo. (95% CI: 2.8, NE)	7.1 mo. (95% CI: 3.9, NE)
Disease Control Rate (DCR)	88% (15/17)	90% (18/20)	84% (16/19)

- At the 8.6 mg/kg dose, the confirmed response rate was 20% with an estimated median PFS of 6.8 months and at the 10 mg/kg dose, the confirmed response rate was 32% with an estimated median PFS of 7.1 months.
- The disease control rate was 88% (49/56) across the expansion doses of 7.2 – 10 mg/kg.
- The doses of 8.6 mg/kg and 10 mg/kg have been prioritized for further evaluation with the goal of selecting a dose or doses for a registrational study.
- Dose optimization at 8.6 mg/kg and 10 mg/kg utilizing AIBW dosing and updated prophylaxis for adverse event management is ongoing.
- At the doses of 11 mg/kg Q3W and 12 mg/kg Q3W, which were not expanded for further evaluation, the overall response rate was 30% (3/10).

Safety:

As of the data cutoff, 93 patients were evaluable for safety including 80 patients across the expansion dose range of 7.2 mg/kg to 10 mg/kg. Varseta-M's safety profile was generally consistent with data presented in Phase 1 dose escalation. Most treatment related adverse events were Grade 1 or Grade 2 in severity.

- No interstitial lung disease, febrile neutropenia or pancreatitis were observed.
- The most common treatment-related adverse event (TRAE) was diarrhea which was generally manageable and reversible.
- In Phase 1 dose expansions starting in Q2 2025, prophylactic strategies for diarrhea management were investigated. In dose optimization starting in Q4 2025, an updated prophylaxis regimen of anti-motility medication (loperamide or diphenoxylate/atropine) plus budesonide was implemented.[3]
- In the 20 patients receiving the updated prophylactic regimen in dose optimization at doses of 8.6 mg/kg and 10 mg/kg, Grade 3 diarrhea was 10%.[4,5]
- Overall, as of the January 16th 2026 data cutoff, in the 80 patients treated at expansion and optimization doses ranging between 7.2 mg/kg to 10 mg/kg, the most common treatment-related adverse events (TRAEs) were diarrhea (68 pts, 19 Gr 3), nausea (44 pts, 4 Gr 3), vomiting (29 pts, 3 Gr 3), fatigue (32 pts, 2 Gr 3), hypokalemia (21 pts, 13 Gr 3+), and anemia (13 pts, 6 Gr 3). Serious treatment related adverse events (SAEs) in > 1 patient included diarrhea (4), vomiting (3), hypokalemia (3), dehydration (3), acute kidney injury (2), and colitis (2).
- As previously reported on August 13, 2025, there was one treatment-related grade 5 acute kidney injury (AKI) in a patient treated at the 7.2 mg/kg dose. The patient had a complex medical history including having a solitary kidney, and the AKI was determined to be secondary to Grade 3 nausea and Grade 2 diarrhea. No other Grade 5 TRAEs have been reported as of the January 16th 2026 data cutoff.
- At the 11 mg/kg and 12 mg/kg doses, there were no dose limiting toxicities in dose escalation. The most common TRAEs across the patients in the 11 mg/kg dose (n=8) and 12 mg/kg dose (n=3) were diarrhea (9 pts, 6 GR 3), nausea, (8 pts, 0 Gr 3), and vomiting (8 pts, 1 Gr 3). Patients treated at the 11 and 12 mg/kg doses did not receive the optimized prophylactic regimen or adjusted ideal body weight dosing.

Varsetatug Masetecan Next Steps:

- Additional efficacy and safety data from the Phase 1 study are expected to be presented at one or more medical meetings in 2026.
- The Company aims to align with the FDA in 2026 on a potential registrational study design for Varseta-M monotherapy in advanced CRC.
- A Phase 1 Varseta-M combination study with bevacizumab in CRC has been initiated and a Phase 1b/2 study in combination with bevacizumab and chemotherapy is expected to start by the end of 2026.
- Initiation of Phase 1 expansion cohort(s) in additional EpCAM-expressing indications is planned for 2H 2026.

CytomX Investor Event Information

Additional details will be provided on the Company's Investor Call on March 16, 2026 at 8 a.m. ET. 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, Inc.

CytomX is a clinical-stage, oncology-focused biopharmaceutical company focused on developing novel conditionally activated, masked PROBODY® therapeutics 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"), cytokines and T-cell engagers. CytomX's clinical-stage pipeline includes varsetatug masetecan (Varseta-M; CX-2051) and CX-801. Varseta-M is a masked, conditionally activated ADC armed with a topoisomerase-1 inhibitor payload and directed toward epithelial cell adhesion molecule (EpCAM). EpCAM is a highly expressed tumor antigen that has previously been undruggable due to expression on normal tissues. Varseta-M is designed to open a therapeutic window for this high potential target and is initially being developed for the treatment of metastatic colorectal cancer. Varseta-M 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. CX-801 is initially being developed for the treatment of metastatic melanoma. CytomX has established strategic collaborations with multiple leaders in oncology, including Amgen, 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 CytomX's 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 and projected cash runway. 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 varsetatug masetecan (Varseta-M; CX-2051) and CX-801, the potential benefits or applications of CytomX's PROBODY ® therapeutic platform, CytomX's planned interactions with the U.S. Food and Drug Administration and the ability to align on a potential registrational study design and regulatory pathway for varsetatug masetecan, 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 varsetatug masetecan and CX-801 and the timing of initial and ongoing data availability for CytomX's clinical trials, including varsetatug masetecan 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 varsetatug masetecan clinical trial 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 varsetatug masetecan 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. Additional applicable risks and uncertainties include those relating to CytomX's 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 March 16, 2026. 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] 96% of patients with an evaluable biopsy had an H score by immunohistochemistry above 250 and all patients had H scores above 200.

[2] Per RECIST v.1.1 criteria

[3] Budesonide is a corticosteroid locally absorbed in the gastrointestinal (GI) tract.

[4] 8.6 mg/kg and 10 mg/kg dosed utilizing adjusted ideal body weight (AIBW).

[5] Based on March 2, 2026 data snapshot.

Source: CytomX Therapeutics Inc.