CytomX Therapeutics, Inc. Logo

CytomX Therapeutics Announces FDA Fast Track Designation for Varsetatug masetecan ("Varseta-M") for Relapsed/Refractory Metastatic Colorectal Cancer (R/R mCRC)

August 27, 2026 at 8:00 AM EDT

- Fast Track Designation follows encouraging Phase 1 data that were previously reported for R/R mCRC -

- Potential Varseta-M monotherapy registrational study in R/R mCRC planned for initiation in 1H 2027 -

SOUTH SAN FRANCISCO, Calif., Aug. 27, 2026 (GLOBE NEWSWIRE) -- CytomX Therapeutics, Inc. (Nasdaq: CTMX), a leader in the field of masked, conditionally activated biologics, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track Designation (FTD) to Varseta-M for the treatment of patients with relapsed/refractory metastatic colorectal cancer. Varseta-M is a potential first-in-class antibody drug conjugate directed toward epithelial cell adhesion molecule (EpCAM) with a topoisomerase-1 inhibitor payload.

"Varseta-M was intentionally designed for patients with colorectal cancer based on the high expression of EpCAM in this cancer type. Receiving Fast Track Designation is an important milestone for the program and reflects its potential to address a highly unmet medical need in patients with relapsed/refractory metastatic colorectal cancer where we continue to work towards a planned first registrational trial in the first half of 2027," said Dr. Sean McCarthy, chairman and CEO of CytomX Therapeutics.

Fast Track Designation is intended to facilitate development and expedite the review of therapies for serious conditions with unmet medical needs.

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, 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 regulatory approvals or commercial opportunity. 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 pipeline, including varsetatug masetecan (Varseta-M), 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 timing or success of a potential registrational study design and regulatory pathway for Varseta-M, CytomX's ability to develop and advance product candidates into and successfully complete clinical trials, including the ongoing and planned clinical trials of Varseta-M alone and in combination with other drugs and the timing of initial and ongoing data availability for CytomX's clinical trials, including Varseta-M, 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 Varseta-M 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; the possibility that CytomX may not be able to realize the full potential of its collaborations; CytomX's dependence on the success of Varseta-M 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 CytomX 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 Quarterly Report on Form 10-Q filed with the SEC on August 6, 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 disclaim 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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