CytomX Therapeutics, Inc. Logo

CytomX Therapeutics Announces First Patient Dosed in Combination Arm of Phase 1 Study of CX-801 plus KEYTRUDA® (pembrolizumab) in Patients with Metastatic Melanoma

May 19, 2025 at 8:00 AM EDT

SOUTH SAN FRANCISCO, Calif., May 19, 2025 (GLOBE NEWSWIRE) -- CytomX Therapeutics, Inc. (Nasdaq: CTMX), a leader in the field of masked, conditionally activated biologics, today announced that the first patient has been dosed with CX-801 in combination with KEYTRUDA® (pembrolizumab), Merck's anti-PD-1 therapy, in the ongoing Phase 1 dose escalation study (NCT06462794) evaluating safety and initial clinical activity in patients with metastatic melanoma.

CX-801 is a dually masked interferon (IFN) alpha-2b PROBODY® cytokine. CX-801 has been intentionally designed by CytomX to harness the power of Interferon alpha-2b's immune stimulating properties in combination with checkpoint inhibition. Interferon alpha-2b has well known single agent anti-cancer activity in multiple tumor types, including in melanoma. However, its use has been limited due to its poor tolerability arising from systemic toxicities. CX-801 is designed to localize the potency of IFN alpha-2b to tumors and reduce systemic toxicities, enabling combination strategies.

CytomX is conducting a focused Phase 1 dose escalation study of CX-801 in metastatic melanoma. The combination arm of the study evaluating CX-801 in combination with KEYTRUDA® has been initiated following successful the clearance of the first three CX-801 monotherapy dose escalation cohorts.

"We are excited to begin evaluating this combination therapy that has the potential to provide significant clinical benefit to patients with PD-1 refractory melanoma, which remains an area of high unmet need," said Dr. Wayne Chu, M.D., chief medical officer of CytomX Therapeutics. "Utilizing CytomX's proprietary conditional activation platform to maintain potency and widen interferon's therapeutic index, CX-801 is well suited to combine with KEYTRUDA® and could become an important component of combination immuno-oncology therapy. We look forward to initial Phase 1a translational and biomarker data in advanced melanoma in the second half of 2025."

KEYTRUDA® is a registered trademark of Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc., Rahway, NJ, USA

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, and was discovered in collaboration with ImmunoGen. 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-801. 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-801 and CX-2051, 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-801 and CX-2051 and the timing of initial and ongoing data availability for our clinical trials, including 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; 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-801 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.

Company Contact:

Chris Ogden
SVP, Chief Financial Officer
cogden@cytomx.com

Investor Contact:
Precision AQ (formerly Stern Investor Relations)
Stephanie Ascher
stephanie.ascher@precisionaq.com

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

Source: CytomX Therapeutics Inc.