CytomX Therapeutics, Inc. Logo

CytomX Therapeutics Announces FDA Clearance of IND Applications for CX-2051, a Probody® Antibody Drug Conjugate (ADC) Targeting EpCAM and CX-801, a Conditionally Activated Interferon Alpha-2b

January 24, 2024 at 8:00 AM EST

- Initiation of CX-2051 Phase 1 clinical study in EpCAM positive tumors including colorectal cancer anticipated in 1H 2024 -

- Initiation of CX-801 Phase 1 clinical study in solid tumors including melanoma, renal, and head and neck squamous cell carcinoma also anticipated in 1H 2024 -

SOUTH SAN FRANCISCO, Calif., Jan. 24, 2024 (GLOBE NEWSWIRE) -- CytomX Therapeutics, Inc. (Nasdaq: CTMX), a leader in the field of conditionally activated, localized biologics, today announced that it has received clearance from the U.S. Food and Drug Administration (FDA) for its Investigational New Drug (IND) applications for the conditionally activated Probody® therapeutics CX-2051, an EpCAM-directed ADC, and CX-801, a dually-masked version of interferon-alpha 2b. CX-2051 has been cleared for the initiation of Phase 1 dose escalation in solid tumors with known EpCAM expression and CX-801 has been cleared for the initiation of Phase 1 dose escalation in solid tumors including melanoma, renal, and head and neck squamous cell carcinoma. Both programs are expected to start Phase 1 studies in the first half of 2024.

“CX-2051 and CX-801 have the potential to address major unmet needs in oncology and we are excited to advance these programs into Phase 1 clinical studies. CX-2051 is an ADC conjugated to a next-generation topoisomerase-1 inhibitor payload that we believe is tailored to certain EpCAM-expressing tumors, including colorectal cancer,” said Wayne Chu, M.D., chief medical officer of CytomX Therapeutics. “CX-801 is designed to overcome previous limitations of interferon-directed therapies due to systemic toxicity and establish CX-801 as a cornerstone of combination regimens, including with checkpoint inhibitors, across a wide range of tumor types,” continued Dr. Chu.

“The parallel advancement of these programs toward the clinic demonstrates the continued high productivity of the CytomX team and the versatile, multi-modality nature of our Probody® platform. The product design principles behind CX-2051 and CX-801 integrate over a decade of continuous innovation and experience at CytomX,” said Sean McCarthy, D.Phil., chief executive officer and chairman of CytomX Therapeutics. “We look forward to the clinical initiation of these programs as we enter a potentially milestone-rich period for the company in 2024 and 2025.”

About CX-2051

EpCAM is a high potential oncology target that has been clinically validated by locally administered, previously approved cancer therapies. However, to date, efforts to generate systemically administered anti-EpCAM therapeutics have not been successful due to toxicities in certain epithelial tissues, notably in the gastrointestinal tract. CX-2051, a conditionally activated ADC, is tailored to optimize the therapeutic index for EpCAM-expressing cancers. The cytotoxic payload utilized in CX-2051 is a derivative of camptothecin, a topoisomerase-1 inhibitor, a class of drug that has shown potent clinical anti-cancer activity in the ADC context for multiple targets. CX-2051 has demonstrated a wide predicted therapeutic index and strong preclinical activity and tolerability in multiple preclinical models, including colorectal cancer. Phase 1 clinical initiation in EpCAM expressing solid tumors is expected in the first half of 2024. Further details on the design and preclinical optimization of CX-2051 can be found here:

Link to 2023 World ADC Conference presentation

About CX-801

Interferon-alpha 2b is an immunotherapeutic cytokine that has demonstrated clinical activity and gained regulatory approval previously in multiple cancer types, including metastatic melanoma, renal cancer and bladder cancer. IFNα2b provides a potentially superior approach to activating anti-tumor immune responses compared to other cytokines. CX-801 is a dually masked, conditionally activated version of IFNα2b that has the potential to become a cornerstone of combination therapy for a wide range of tumor types, including in traditionally immuno-oncology sensitive as well as insensitive (cold) tumors. Phase 1 initiation for CX-801 solid tumors including melanoma, renal, and head and neck squamous cell carcinoma anticipated in the first half of 2024. Further details on the design and preclinical optimization of CX-801 can be found here:

Link to 2023 SITC poster

About CytomX Therapeutics

CytomX is a clinical-stage, oncology-focused biopharmaceutical company focused on developing novel conditionally activated 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 and checkpoint inhibitors. CytomX’s clinical pipeline includes the cancer immunotherapeutic candidates CX-904 and BMS-986288. CX-904, partnered with Amgen, is a conditionally activated T-cell-engaging antibody targeting the epidermal growth factor receptor (EGFR) on tumor cells and the CD3 receptor on T cells. BMS-986288, partnered with Bristol Myers Squibb, is a conditionally activated CTLA-4-targeting antibody that is a non-fucosylated version of ipilimumab. In addition, CytomX has a diverse, emerging portfolio of wholly-owned drug candidates including CX-2051, a conditionally activated ADC directed toward epithelial cell adhesion molecule, EpCAM, with potential applicability across multiple EpCAM-expressing epithelial cancers, and CX-801, an interferon alpha-2b Probody cytokine with broad potential applicability in traditionally immuno-oncology sensitive as well as insensitive 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 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-2051, CX-801, BMS-986288, and CX-904, 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 BMS-986288 and 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 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 BMS-986288, 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 November 7, 2023. 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.

CytomX Contact:
Chris Ogden
SVP, Finance and Accounting
cogden@cytomx.com
Direct: (317) 767-4764

Investor and Media Contact:
Stern Investor Relations
Stephanie Ascher
stephanie.ascher@sternir.com
212-362-1200

Source: CytomX Therapeutics Inc.