CytomX Therapeutics, Inc. Logo

CytomX Therapeutics Announces FDA Clearance of Investigational New Drug Application for CX-904 for the Treatment of Advanced Solid Tumors

January 19, 2022

- CX-904 is CytomX's first T-cell-engaging bispecific antibody and the sixth Probody® therapeutic candidate to enter the clinic -

SOUTH SAN FRANCISCO, Calif., Jan. 19, 2022 (GLOBE NEWSWIRE) -- CytomX Therapeutics, Inc. (Nasdaq: CTMX), a leader in the field of conditionally activated therapeutics, today announced that the U.S. Food and Drug Administration (FDA) has cleared the company's Investigational New Drug (IND) application for CX-904, an EGFRxCD3 T-cell-engaging bispecific antibody being co-developed by CytomX and Amgen.

"The impressive innovation of CX-904's design and its advancement into the clinical setting underscores our commitment to destroying cancer differently. The CX-904 IND also marks the sixth therapeutic candidate and the third treatment modality overall to enter the clinic from our versatile and tunable Probody platform, reinforcing our leadership in the field of conditional activation of biologic therapeutics," said Sean McCarthy, D.Phil., president, chief executive officer and chairman of CytomX Therapeutics. "Our masked Probody T-cell engagers are designed to harness the power of this highly potent modality. We are eager to initiate the Phase 1 dose-escalation study for CX-904 as the leading edge of our broad efforts to bring conditionally activated bispecifics to patients with advanced solid tumors."

T-cell-engaging bispecific antibodies have tremendous potential for the treatment of solid tumors by directing T cells against tumor antigens, including the epidermal growth factor receptor (EGFR). However, the extraordinarily high potency of these agents can narrow their therapeutic window significantly when their target is present on normal tissues. CX-904 is a conditionally activated T-cell bispecific antibody designed to bind to both EGFR on cancer cells and to the CD3 receptor on T cells selectively in the tumor microenvironment. In preclinical studies, CytomX's conditionally activated Probody EGFRxCD3 bispecific therapeutics demonstrated potent anti-tumor activity and strong improvement in safety versus EGFRxCD3 bispecifics without Probody masking.[1]

About CytomX Therapeutics, Inc.
CytomX is a clinical-stage, oncology-focused biopharmaceutical company dedicated to destroying cancer differently. By pioneering a novel class of conditionally activated biologics, powered by its Probody® technology platform, CytomX's goal is to transcend the limits of current cancer treatments and successfully leverage therapeutic targets that were once thought to be inaccessible. CytomX's robust and differentiated pipeline includes the wholly-owned praluzatamab ravtansine (CX-2009), an investigational conditionally activated antibody-drug conjugate (ADC) directed toward CD166, and CX-2029, an investigational conditionally activated ADC directed toward CD71 co-developed with AbbVie. These two programs are currently being evaluated in Phase 2 studies, targeting a variety of late-stage, difficult-to-treat cancer types, including breast cancer for praluzatamab ravtansine, and squamous non-small cell lung cancer, and head and neck squamous cell carcinoma for CX-2029. CytomX's clinical pipeline also includes cancer immunotherapeutic candidates against validated targets such as the CTLA-4-targeting Probody therapeutics, BMS-986249 and BMS-986288, partnered with Bristol Myers Squibb, and our wholly-owned conditionally activated anti-PD-L1 antibody, pacmilimab (CX-072), as well as the Amgen-partnered CX-904, a conditionally activated T-cell-engaging bispecific antibody against the epidermal growth factor receptor on tumor cells and the CD3 receptor on T cells. In addition, CytomX has a diverse preclinical portfolio and strategic collaborations with other leaders in oncology, including AbbVie, Amgen, Astellas, and Bristol Myers Squibb. 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. 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-904, the potential benefits or applications of CytomX's Probody platform technology, CytomX's ability to develop and advance product candidates into and successfully complete clinical trials, including the ongoing and planned clinical trials of praluzatamab ravtansine, CX-2029, BMS-986249, BMS-986288, pacmilimab, and CX-904, and the timing of the commencement of clinical trials, initial data, investigational new drug applications 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 Platform technology; CytomX's clinical trial product candidates, including CX-904, 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 risk that the COVID-19 worldwide pandemic may continue to negatively impact the business, research and clinical operations of CytomX or its partners, including the development of preclinical drug candidates due to delays in and disruption of research activities and the development of clinical drug candidates due to delays in or disruption of clinical trials, including impacts on the enrollment of patients in clinical trials or other clinical trial disruptions; the possibility that the results of 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 praluzatamab ravtansine, CX-2029, BMS-986249, BMS-986288, pacmilimab, and CX-904; CytomX's reliance on third parties for the manufacture of the Company's product candidates; and possible regulatory developments in the United States and foreign countries. 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 4, 2021. 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.

Reference:

1. Boustany L, La Porte S, Wong L, et al. EGFR-CD3 Bispecific Probody™ Therapeutic Induces Tumor Regressions and Increases Maximum Tolerated Dose > 60 fold in Preclinical Studies. Poster presented at: AACR-NCI-EORTC International Conference on Molecular Targets; 2017 Oct. 26-30; Philadelphia, PA.

https://cytomx.com/wp-content/uploads/CytomX-PbTCB_AACR_NCI_EORTC_2017_FINAL.pdf

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Source: CytomX Therapeutics Inc.