CytomX Therapeutics, Inc. Logo

CytomX Therapeutics Outlines 2024 Company Priorities and Milestones

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- CX-904 (EGFRxCD3 T-cell engager) initial Phase 1a dose escalation data anticipated in the 2nd half of 2024 -

- IND application filed for conditionally activated EpCAM-directed ADC (CX-2051) with Phase 1 initiation in EpCAM positive tumors expected in the 1st half of 2024 -

- IND application filed for conditionally activated interferon alpha-2b (CX-801) with Phase 1 initiation as monotherapy and in combination with PD-(L)1 anticipated in the 1st half of 2024 -

- Broad pipeline progress anticipated within research and development partnerships including ongoing Phase 2 clinical trial of anti-CTLA-4 Probody® BMS-986288 -

SOUTH SAN FRANCISCO, Calif., Jan. 04, 2024 (GLOBE NEWSWIRE) -- CytomX Therapeutics, Inc. (Nasdaq: CTMX), a leader in the field of conditionally activated, localized biologics, today announced its 2024 company priorities and anticipated milestones for its wholly-owned and partnered pipeline.

"With INDs recently filed for wholly-owned programs, CX-2051 and CX-801, and continued progress in dose escalation with our Probody® T-Cell engager, CX-904, CytomX is well positioned as we enter 2024. Our current lead programs build on more than a decade of Probody platform experience at CytomX and integrate key design elements that leverage previously validated oncology targets, potent effector mechanisms and tailored masking strategies," said Sean McCarthy, D.Phil., chief executive officer and chairman of CytomX Therapeutics. "We believe our multi-modality Probody therapeutic pipeline will address major unmet medical needs in the treatment of cancer. CytomX is entering a potentially milestone-rich period in 2024 and 2025 during which we aim to generate proof of concept clinical data across our lead programs that point the way to future registrational studies."

"CytomX's multi-modality pipeline is highly relevant at this moment in time in oncology R&D. CX-904 is a potentially differentiated EGFR-CD3 T-cell engager in an ongoing Phase 1 clinical trial and, with both CX-2051 and CX-801 also expected to enter the clinic in 2024, we have a broad opportunity to make a meaningful difference in the treatment of cancer," said Wayne Chu, M.D., chief medical officer of CytomX Therapeutics. Continued Dr. Chu, "CX-2051 is an ADC designed to truly unlock EpCAM as an anti-cancer target and we believe the topoisomerase-1 inhibitor payload may be an ideal effector mechanism for multiple EpCAM expressing tumors. CX-801 is a powerful immune-stimulating agent with potential to mitigate historical clinical limitations of cytokine therapies due to toxicity. Our vision is for CX-801 to become a cornerstone of combination regimens for a wide range of tumor types including those that have either stopped responding to, or have failed to respond to, prior immunotherapy. CytomX's lead therapeutic candidates have the potential for significant impact and we will be working tirelessly to bring these therapies forward for the benefit of patients."

CX-904, EGFRxCD3 T-cell Engager

CX-904 is a conditionally activated Probody T-cell engager designed to target the epidermal growth factor receptor (EGFR) on cancer cells and the CD3 receptor on T cells within the tumor microenvironment. CX-904 is partnered with Amgen in a global co-development alliance and is being evaluated in an ongoing Phase 1 study in patients with advanced solid tumors that have known EGFR expression. Backfilling of certain dose escalation cohorts has been initiated and dose ranging continues. Initial Phase 1a dose escalation data is anticipated in the second half of 2024. The Phase 1a data will inform a potential decision during 2024 to initiate Phase 1b expansion cohorts in specific EGFR positive tumor types. The decision to potentially initiate Phase 1b expansion cohorts will be taken in conjunction with Amgen.

CX-2051, Antibody Drug Conjugate (ADC) targeting EpCAM

EpCAM is a high potential oncology target that has been clinically validated by locally administered, previously approved cancer therapies. However, efforts to generate systemically administered anti-EpCAM therapeutics have, to date, 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 epithelial 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. An IND application has been filed for this program and clinical initiation in EpCAM expressing solid tumors is expected in the first half of 2024.

CX-801, Interferon-alpha 2b (IFNα2b)

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. An IND application has been filed for this program. Phase 1 initiation for CX-801 as a monotherapy and in combination with checkpoint inhibition is expected in the first half of 2024.

BMS-986288, Non-fucosylated CTLA-4-targeting Probody Therapeutic

Bristol Myers Squibb continues to make progress evaluating the next-generation CTLA-4 program, BMS-986288, a non-fucosylated CTLA-4 targeting Probody therapeutic. In 2023, Bristol Myers Squibb prioritized the BMS-986288 Probody® therapeutic program as its lead next-generation CTLA-4 program and advanced the program to Phase 2 clinical studies. BMS-986288 is designed to be more potent than ipilimumab (YERVOY®) and to leverage CytomX's Probody therapeutic technology to potentially localize clinical activity to tumors while reducing systemic toxicity. The ongoing Phase 2 clinical evaluation of BMS-986288 includes proof of concept studies for microsatellite stable (MSS) colorectal cancer (CRC) and non-small cell lung cancer (NSCLC). Bristol Myers Squibb anticipates data from the study will be available in 2024[1]. CytomX and Bristol Myers Squibb also

continue to collaborate on multiple preclinical research programs.

Research and Development Partnerships

CytomX has multiple active research and development partnerships with major biotechnology and pharmaceutical companies (Amgen, Astellas, Bristol Myers Squibb, Moderna, Regeneron). Throughout 2023, CytomX made substantial progress across its research partnerships including the commencement of programs under its new alliances with Regeneron and Moderna. In January 2023, CytomX earned a $5 million milestone for the first T-cell engager clinical candidate nominated in the Astellas collaboration. CytomX has a consistent track record of forming new strategic research and development alliances and achieving preclinical research and clinical milestones. Partnering is expected to remain an important part of the Company's strategy in 2024 and beyond.

2024 PRIORITIES AND KEY MILESTONES

CytomX enters 2024 in a strong strategic position and with significant momentum in its pipeline. The company's key pipeline programs are progressing towards clinical proof of concept and key milestones in 2024 including:

- **CX-904 (EGFRxCD3):** Continued enrollment into Phase 1a dose escalation. Phase 1a initial dose escalation data are expected in the second half of 2024. These data are expected to inform a potential decision, to be taken with Amgen, to initiate Phase 1b expansion cohorts in specific EGFR positive tumor types in 2024.
- **CX-2051 (EpCAM):** Initiation of Phase 1 dose escalation in solid tumors with known EpCAM expression including metastatic colorectal cancer as one priority indication is expected in the first half of 2024.
- **CX-801 (IFNα2b):** Initiation of Phase 1 dose escalation in solid tumors including melanoma, renal, and head and neck squamous cell carcinoma is expected in the first half of 2024.
- **Next-Generation CTLA-4 Program:** Continued clinical progress for BMS-986288 including proof-of-concept studies in MSS CRC and NSCLC. Bristol Myers Squibb anticipates data from the study will be available in 2024.
- **Collaborations:** Continuation of drug discovery and development activities with Bristol Myers Squibb, Amgen, Astellas, Regeneron, and Moderna with potential pre-clinical and clinical milestones possible in 2024 and and beyond.
- **Financial:** CytomX ended the third quarter of 2023 with $194 million of cash and cash equivalents. Cash runway is projected to the second half of 2025, excluding any potential milestones from existing collaborations or new business development.

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 that has 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 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, BMS-986288, CX-904, and CX-801, 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.

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[1] Bristol Myers Squibb 2023 R&D Day, September 14, 2023

Source: CytomX Therapeutics Inc.