CytomX Therapeutics, Inc. Logo

CytomX Therapeutics Announces Phase 2 Results for Praluzatamab Ravtansine in Breast Cancer

July 6, 2022

- Study meets primary endpoint of objective response rate in HR+/HER2-non-amplified breast cancer -

- Secondary endpoints including clinical benefit rate at 24 weeks and median progression-free survival were 40 percent and 2.6 months, respectively -

- Arm B did not pass protocol-defined futility boundary in triple-negative breast cancer; enrollment to Arms B and C to be discontinued -

- Company to host conference call and webcast today at 5:00 pm ET / 2:00 pm PT -

SOUTH SAN FRANCISCO, Calif., July 06, 2022 (GLOBE NEWSWIRE) -- CytomX Therapeutics, Inc. (Nasdaq: CTMX), a leader in the field of conditionally activated oncology therapeutics, today announced that the Phase 2 study of praluzatamab ravtansine in patients with hormone receptor-positive (HR+)/human epidermal growth factor receptor 2 (HER2)-non-amplified breast cancer (Arm A) met its primary efficacy endpoint of confirmed objective response rate (ORR) of greater than 10 percent by central radiology review. Praluzatamab ravtansine is a DM4-conjugated, conditionally activated antibody-drug conjugate (ADC) targeting CD166 and is wholly owned by CytomX.

As of the data cutoff on May 13, 2022, 47 patients unselected for CD166 expression with advanced HR+/HER2-non-amplified breast cancer were evaluable for the primary efficacy endpoint. The ORR by central radiology review was 15 percent. Clinical benefit rate at 24 weeks by investigator (CBR24), as defined in the protocol as any response (confirmed or unconfirmed) or stable disease for 24 weeks, was 40 percent; median progression-free survival was 2.6 months. All patients in Arm A were treated at the initial Phase 2 starting dose of 7 mg/kg administered every three weeks. Arm B did not pass protocol-defined futility boundary (ORR was less than 10%) in patients with advanced triple-negative breast cancer (TNBC) and enrollment into Arms B and C will be discontinued.

As of this data cut, the safety profile of praluzatamab ravtansine in Arm A was generally consistent with toxicities observed in Phase 1 and with the DM4 payload; namely, high-grade toxicities or toxicities resulting in dose modifications were predominantly ocular or neuropathic in nature. Thirty percent of patients discontinued treatment for an adverse event (AE). Grade 3+ ocular and neuropathic toxicities were 15 and 10 percent, respectively. Arm B evaluated both 7 mg/kg and 6 mg/kg in patients with TNBC. The toxicity profile of 7 mg/kg starting dose was consistent with Arm A. In the 6 mg/kg cohort, no patients discontinued treatment for an AE and Grade 3+ ocular or neuropathic related events were lower at 3, and 0 percent, respectively. Biomarker analysis is ongoing. CytomX intends to submit data from this study for presentation at a medical conference in the second half of 2022.

“These results from our Phase 2 evaluation of praluzatamab ravtansine support single-agent activity of this novel drug candidate in hormone receptor-positive breast cancer where significant unmet need remains,” said Sean McCarthy, D.Phil., chief executive officer and chairman at CytomX Therapeutics. “However, we do not believe the median progression-free survival at 7 mg/kg supports further evaluation at this dose. While we are encouraged by the emerging safety profile of 6 mg/kg, we do not plan to further advance this program alone given current financial market conditions and will be seeking a partnership.”

Kathy D. Miller, MD, Ballvé Lantero Professor of Oncology, Indiana University Simon Comprehensive Cancer Center, Indianapolis, Indiana, and lead investigator of the Phase 2 study stated, “In this Phase 2 study, praluzatamab ravtansine showed single-agent activity in an unselected population of patients with advanced HR+/HER2-non-amplified breast cancer; additional clinical studies at 6 mg/kg are warranted.”

Conference Call & Webcast
CytomX management will host a conference call and a simultaneous webcast today at 5:00 pm ET (2:00 pm PT) to discuss these results. Participants may register for the conference call here and are advised to do so at least 10 minutes prior to joining the call. A live webcast of the call can be accessed via the Events and Presentations page of CytomX's website at https://ir.cytomx.com/events-and-presentations.

About Praluzatamab Ravtansine
Praluzatamab ravtansine is a conditionally activated antibody-drug conjugate (ADC) comprised of a CD166-directed humanized monoclonal antibody conjugated to the maytansinoid DM4, a tubulin inhibitor. Praluzatamab ravtansine utilizes CytomX Probody® platform technology, which incorporates a masking peptide to cover and block the cellular binding region of the antibody. Tethered to the antibody via a protease-cleavable linker, the masking peptide is designed to be removed in a protease-rich tumor microenvironment, enabling the ADC to be unmasked and engage its target to deliver the toxic DM4 payload inside tumor cells. The goal is to have praluzatamab ravtansine remain inert while in circulation to limit binding in healthy tissues until it is activated by tumor-associated proteases. Praluzatamab ravtansine was evaluated in a three-arm Phase 2 study (NCT04596150) in patients with hormone receptor-positive/HER2-non-amplified breast cancer and patients with triple-negative breast cancer.

About the Phase 2 Study of Praluzatamab Ravtansine in Breast Cancer (NCT04596150)
Arm A of the study evaluated praluzatamab ravtansine as monotherapy (7 mg/kg, Q3W) in patients with inoperable, locally advanced or metastatic hormone receptor-positive/human epidermal growth factor receptor 2 (HER2)-non-amplified breast cancer. Patients received 0 to 2 prior cytotoxic chemotherapies in the inoperable, locally advanced, or metastatic setting, regardless of the level of CD166 expression.

Arm B assessed praluzatamab ravtansine as a single agent (6 or 7 mg/kg, Q3W) in patients with inoperable, locally advanced or metastatic triple-negative breast cancer (TNBC). Patients received 1 to 3 prior lines of chemotherapy for inoperable, locally advanced, or metastatic disease and had CD166 expression.

Arm C studied praluzatamab ravtansine (6 mg/kg, Q3W) in combination with pacmilimab (1200 mg, Q3W), CytomX’s proprietary conditionally activated anti-PD-L1 antibody, in patients with TNBC. Eligibility was the same as Arm B with the additional requirement that patients’ tumors were programmed death-ligand 1 (PD-L1)-positive by an FDA-approved test.

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 by successfully leveraging therapeutic targets that were once thought to be inaccessible. CytomX's robust and differentiated pipeline includes the wholly-owned praluzatamab ravtansine, an investigational conditionally activated antibody-drug conjugate (ADC) directed toward CD166, and CX-2029, an investigational conditionally activated ADC directed toward CD71 being developed in collaboration 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, as well as CX-904, a conditionally activated T-cell-engaging bispecific antibody targeting the epidermal growth factor receptor on tumor cells and the CD3 receptor on T cells, which is partnered with Amgen. In addition, CytomX has a diverse preclinical portfolio and strategic collaborations with multiple 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.

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' other product candidates, including praluzatamab ravtansine, 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 clinical trial of praluzatamab ravtansine, CX-2029, BMS-986249, BMS-986288, pacmilimab, and CX-904, the timing of ongoing data availability, and our ability to obtain a partner for praluzatamab ravtansine. 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 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 May 5, 2022. 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.

Probody is a U.S. registered trademark of CytomX Therapeutics, Inc.

Investor Contact:
Chau Cheng, PhD MBA
VP, Investor Relations & Corp. Communications
ccheng@cytomx.com
Direct: (650) 273-4999

Media Contact:
Bret Coons
Director, Corporate Communications
bcoons@cytomx.com
Direct: (650) 528 2929

Source: CytomX Therapeutics Inc.