CytomX Therapeutics, Inc. Logo

CytomX Therapeutics Announces Preliminary Results for Ongoing Phase 2 Expansion Study of CX-2029, a First-in-Class Antibody-Drug Conjugate Candidate Targeting the Transferrin Receptor, CD71

December 20, 2021

-Objective response rate of 18.8 percent and disease control rate of 87.5 percent in unselected advanced squamous non-small cell lung cancer. Enrollment continues-

-Enrollment completed in advanced head and neck squamous cell carcinoma with objective response rate of 4.0 percent and disease control rate of 56.0 percent-

-Adverse event profile consistent with Phase 1 observations-

-Company to host conference call and webcast today at 5 p.m. ET / 2 p.m. PT-

SOUTH SAN FRANCISCO, Calif., Dec. 20, 2021 (GLOBE NEWSWIRE) -- CytomX Therapeutics, Inc. (Nasdaq: CTMX), a leader in the field of conditionally activated therapeutics, today announced preliminary Phase 2 results in patients with either advanced squamous non-small cell lung cancer (sqNSCLC) or head and neck squamous cell carcinoma (HNSCC), who were treated with CX-2029 – a CD71-directed conditionally activated antibody-drug conjugate (ADC) being co-developed by CytomX and AbbVie.

"We are pleased to report these first results from the ongoing Phase 2 expansion study of CX-2029, a novel ADC developed with the CytomX Probody Therapeutic platform. We are encouraged that the response rate in heavily-pretreated and unselected sqNSCLC patients at this recent data cut off is trending with our stated target of 20% and enrollment in this tumor type continues towards our goal of 25 efficacy-evaluable patients. No new safety signals were observed and we are also encouraged by the low discontinuation rate due to adverse events. These preliminary results corroborate our previous Phase 1 observations and open a potential sqNSCLC commercial opportunity in the growing post-checkpoint inhibitor setting where there are limited treatment options," said Sean McCarthy, D.Phil., president, chief executive officer and chairman of CytomX Therapeutics. "We continue to work closely with our partner, AbbVie, and look forward to completing the expansion phase of the CX-2029 development program and providing further data updates in 2022."

As of the data cutoff on October 29, 2021, 23 patients with sqNSCLC and 29 patients with HNSCC had received at least one dose of CX-2029 at 3 mg/kg (safety population), of whom 16 sqNSCLC patients and 25 HNSCC patients had at least one post baseline assessment (efficacy-evaluable population), including, per protocol, 5 patients (2 sqNSCLC and 3 HNSCC) enrolled in the previously reported Part B (tumor biopsy cohorts). The median follow-up time was 3.8 months (range, 0.2-20.1). In the 16 efficacy evaluable patients with sqNSCLC, objective response rate (ORR) by local investigator was 18.8 percent, including two confirmed partial responses (PRs) and one unconfirmed PR that confirmed seven days after the data cutoff. Two of these responses were ongoing and the third had a response duration of 5.6 months. The disease control rate (DCR), which includes patients with a complete response, PR or stable disease, was 87.5 percent. In the 25 efficacy evaluable patients with HNSCC, there was one confirmed PR (ORR 4.0%) and a DCR of 56.0 percent, including one unconfirmed PR. Below is a summary table.

	sqNSCLC			HNSCC		
	Safety Evaluable	Efficacy Evaluable	Confirmed PR	Safety Evaluable	Efficacy Evaluable	Confirmed PR
Part B	2	2	1	3	3	1
Part C	21	14	2*	26	22	0**
Total	23	16	3	29	25	1
ORR			18.8%			4.0%

*Includes one unconfirmed PR that confirmed after the data cutoff. **One unconfirmed PR was observed (will not confirm).

Safety analysis was conducted on all sqNSCLC and HNSCC patients who received at least one dose of CX-2029 at 3 mg/kg (N=52), either in Part B (N=5), or in the expansion cohorts (N=47). The median number of prior therapies in the metastatic setting was two (range, 1-5) for sqNSCLC and three (range, 1-9) for HNSCC. All patients with sqNSCLC had received prior platinum and prior checkpoint inhibition; in HNSCC, all but one patient received prior platinum and all but two, prior checkpoint inhibition.

The safety profile was consistent with previous Phase 1 observations, with no new safety signals identified. The most common treatment-related adverse events (TRAEs) in 10% or more of patients (All Grade, Grade 3) were anemia (78.8%, 67.3%), infusion related reactions (69.2%, 3.8%), fatigue (19.2%, 1.9%), and nausea (13.5%, 0.0%), and decreased neutrophil count (13.6%, 9.6% (plus one Grade 4 event 1.9%)). The most common reason for treatment discontinuation was disease progression (44.2%), three patients (5.8%) discontinued for a treatment-related adverse event (anemia; 2 Grade 2, 1 Grade 3). TRAEs leading to dose interruption or reduction were 40.4% and 34.6%, respectively. Thirteen patients, eight with sqNSCLC and five with HNSCC, were still on treatment as of the data cut off.

Conference Call & Webcast
CytomX management will host a conference call and a simultaneous webcast today at 5 p.m. ET (2 p.m. PT) to discuss these results. To join the conference call, please dial (877) 809-6037 (domestic) or (615) 247-0221 (international) and reference the conference ID 8065625. 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. A replay of the webcast will also be available for 30 days following the call.

About CX-2029
Co-developed by CytomX and AbbVie, CX-2029 is a conditionally activated antibody-drug conjugate (ADC) comprised of a CD71-directed humanized monoclonal antibody conjugated via a cleavable linker to the microtubule inhibitor, monomethyl auristatin E (MMAE), with a drug-to-antibody ratio (DAR) of 2. A key feature of CX-2029 is its masking peptide, which covers and blocks 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 then unmasked ADC to engage its target and deliver the toxic payload inside tumor cells. The goal is to have CX-2029 remain inert while in circulation, with the intent of limiting binding in healthy tissues until it is activated by tumor-associated proteases. CX-2029 is being evaluated as monotherapy in a Phase 2 expansion study (NCT03543813) designed to enroll patients in four cohorts; squamous non-small cell lung cancer, squamous head and neck cancer, esophageal and gastroesophageal junction cancers (both adenocarcinoma and squamous histologies), and diffuse large B-cell lymphoma.

About CytomX Therapeutics

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). 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-2029, 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 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, and pacmilimab; 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.

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

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