Context Therapeutics® Nominates CTIM-76 Bispecific Antibody Candidate to Develop Treatment for Claudin 6-Positive Solid Tumors

November 29, 2022

CTIM-76 named as lead candidate to target Claudin 6 positive cancers

IND submission expected in Q1 2024

Context to host webinar on Thursday, December 1, 2022, at 11 a.m. ET

PHILADELPHIA, Nov. 29, 2022 (GLOBE NEWSWIRE) -- Context Therapeutics Inc. ("Context" or the "Company") (Nasdaq: CNTX), a women's oncology company developing novel treatments for breast and gynecologic cancers, today announced the selection of CTIM-76, a T cell-engaging bispecific antibody, as its lead clinical development candidate to target Claudin 6 (CLDN6) positive cancers, resulting from its research collaboration and licensing agreement with Integral Molecular.

CLDN6 is differentially expressed on cancer cells with no or very low expression in normal, healthy tissue. CLDN6-enriched cancers include ovarian, endometrial, testicular, and gastric, among others. With the potential to reach a large patient population and selective expression on cancer cells, CLDN6 has emerged as an exciting drug target.

Context's lead candidate, CTIM-76, is a CLDN6 x CD3 bispecific antibody that incorporates a highly selective CLDN6 binding arm and a CD3 binding single-chain Fv domain in an IgG format with a silenced Fc that is designed to be functionally monovalent to avoid aberrant T-cell activation and to enhance the safety profile. Research has demonstrated that CTIM-76 is potent with specific lysis of CLDN6+ cancer cells over normal cells and can activate cytotoxic T cells without concomitant activation of free cytokines – critical determinants of immunotherapy safety and activity. Preclinical studies suggest the potential for convenient dosing with low immunogenicity risk and manufacturing can be scalable to address the significant number of patients who are potentially eligible for CTIM-76 therapy.

"This year has been marked by several exciting and significant milestones for Context, culminating in naming our lead CLDN6 clinical development candidate, CTIM-76, a bispecific antibody showing high selectivity for CLDN6," said Martin Lehr, CEO of Context Therapeutics. "We selected this bispecific based on the specificity which suggests its potential to address the need for potent therapeutic modalities for cancer without compromising patient safety. With the selection of CTIM-76 as our lead CLDN6 candidate, we are well-positioned to rapidly advance our clinical development plan in CLDN6-positive tumors including, but not limited to, ovarian cancer. We have initiated IND-enabling studies and expect to submit our Investigational New Drug Application (IND) for CTIM-76 to the U.S. Food and Drug Administration in Q1 2024."

"Despite being an attractive target, therapeutic monoclonal antibodies (MAbs) targeting CLDN6 are difficult to discover due to an abundance of closely related family members and an absolute need for high specificity. Context and Integral Molecular have been able to isolate and optimize rare antibodies against CLDN6 that do not cross-react with other CLDN family members," said Joseph Rucker, Ph.D., VP of R&D at Integral Molecular.

R&D Webinar
On Thursday, December 1, 2022, at 11 a.m. ET, members of the Context team, including management, and Integral Molecular will host a webinar to discuss the selection process and nomination of CTIM-76. There will be a question-and-answer period following the formal presentation. To register for the webinar, please visit https://edisongroup.zoom.us/webinar/register/WN_Am1qwkDwRiSYJm51SpP-TQ.

About Context Therapeutics®
Context Therapeutics Inc. (Nasdaq: CNTX) is a clinical-stage biopharmaceutical company committed to advancing medicines for female cancers. The Company's pipeline includes small molecule and bispecific antibody drug candidates that target cancer signaling pathways. Onapristone extended release (ONA-XR), a novel, first-in-class potent and selective progesterone receptor antagonist, is currently in three Phase 2 clinical trials and one Phase 1b/2 clinical trial in hormone-driven breast, ovarian, and endometrial cancers. Context is also developing CTIM-76, a selective Claudin 6 (CLDN6) x CD3 bispecific antibody for CLDN6 positive tumors, currently in preclinical development. Context is headquartered in Philadelphia. For more information, please visit www.contexttherapeutics.com or follow the Company on Twitter and LinkedIn.

Forward-looking Statements
This press release contains "forward-looking statements" that involve substantial risks and uncertainties for purposes of the safe harbor provided by the Private Securities Litigation Reform Act of 1995. Any statements, other than statements of historical fact, included in this press release regarding strategy, future operations, prospects, plans and objectives of management, including words such as "may," "will," "expect," "anticipate," "plan," "intend," and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) are forward-looking statements. These include, without limitation, statements regarding (i) the selectivity, dosing convenience, potency, binding, scalable manufacturing, and safety profile of CTIM-76, (ii) the expectation to have an IND submission for CTIM-76 in the first quarter of 2024, (iii) the results of our IND-enabling studies and clinical trials, (iv) the potential benefits of our product candidates, (v) the likelihood data will support future development, and (vi) the likelihood of obtaining regulatory approval of our product candidates. Forward-looking statements in this release involve substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by the forward-looking statements, and we, therefore cannot assure you that our plans, intentions, expectations or strategies will be attained or achieved. Other factors that may cause actual results to differ from those expressed or implied in the forward-looking statements in this press release are discussed in our filings with the U.S. Securities and Exchange Commission, including the section titled "Risk Factors" contained therein. Except as otherwise required by law, we disclaim any intention or obligation to update or revise any forward-looking statements, which speak only as of the date they were made, whether as a result of new information, future events or circumstances or otherwise.

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