Atossa Therapeutics Announces Sponsored Research Agreement with Weill Cornell Medicine to Address Treatment Challenges in Triple Negative Breast Cancer

July 6, 2023 1:15 PM EDT

SEATTLE, July 06, 2023 (GLOBE NEWSWIRE) -- Atossa Therapeutics, Inc. (Nasdaq: ATOS), a clinical stage biopharmaceutical company developing innovative proprietary medicines to address significant unmet needs in oncology with a focus on breast cancer, today announces a strategic, sponsored research agreement with Weill Cornell Medicine to study the potential of inducing estrogen receptor (ER) expression in triple-negative breast cancer (TNBC). The goal of this research is to determine if treating TNBC with extracellular vesicles carrying the ER will convert the tumor to ER+ and render it sensitive to treatment with Selective Estrogen Receptor Modulators (SERM), including Atossa's proprietary (Z)-endoxifen.

The research project will be led by David Lyden, M.D., Ph.D., the Stavros S. Niarchos Professor in Pediatric Cardiology and Director of the Department of Pediatrics' Physician Scientist Training Program at Weill Cornell Medicine. Dr. Lyden's laboratory is focused on the molecular pathways activated by tumor extracellular vesicle uptake at the metastatic site and identifying potential therapeutic targets to thwart metastasis. His work has led to a new understanding of how primary tumor cells dictate their own metastases, by decoding how cancer-derived extracellular vesicles mediate intercellular communication. Most recently, Dr. Lyden has identified specific extracellular vesicle subpopulations and discovered a new subset of particles known as exomeres, which collectively have distinct functional roles in the systemic effects of cancer.

"We look forward to working with Atossa and think this project could provide proof of principle for novel approaches to estrogen receptor reinduction in triple negative breast cancer," said Dr. Lyden. "If we are able to change the cancer phenotype and turn on the estrogen receptor, we could then treat these patients with hormone therapy, which is more effective than currently approved treatments for triple-negative breast cancer."

"Triple-negative breast cancer grows and spreads faster than other forms of breast cancer, disproportionately affects Black and Hispanic women and has a higher risk of recurrence," said Dr. Steven Quay, Atossa's President and Chief Executive Officer. "It's called triple-negative breast cancer because it does not have any of the receptors that are commonly found in most breast cancers. This makes triple-negative breast cancer particularly difficult to treat because drugs that target estrogen, progesterone, or the human epidermal growth factor protein are ineffective. Activating the estrogen receptor and converting the tumor to ER+ would fundamentally transform the treatment paradigm for these patients."

About Triple-Negative Breast Cancer
Triple-negative breast cancer (TNBC) accounts for about 10-15% of all breast cancers, which amounts to almost 200,000 cases worldwide each year. The term triple-negative breast cancer refers to the fact that the cancer cells don't have estrogen or progesterone receptors (ER or PR) and also don't make any or much of the human epidermal growth factor receptor 2 (HER2) protein. The tumor cells test "negative" on all three tests. These cancers tend to be more common in women who are younger than age 40, are Black or Hispanic, or who have a BRCA1 mutation. TNBC differs from other types of invasive breast cancer in that it tends to grow and spread faster, has fewer treatment options, has a higher risk of recurrence, and tends to have a worse prognosis.

About (Z)-Endoxifen
(Z)-endoxifen is the most active metabolite of the FDA approved Selective Estrogen Receptor Modulator (SERM), tamoxifen. Studies by others have demonstrated that the therapeutic effects of tamoxifen are driven in a concentration-dependent manner by (Z)-endoxifen. In addition to its potent anti-estrogen effects, (Z)-endoxifen at higher concentrations has been shown to target PKCβ1, a known oncogenic protein.

Atossa is developing a proprietary oral formulation of (Z)-endoxifen that does not require liver metabolism to achieve therapeutic concentrations and is encapsulated to bypass the stomach as acidic conditions in the stomach convert a greater proportion of (Z)-endoxifen to the inactive (E)-endoxifen. Atossa's (Z)-endoxifen has been shown to be well tolerated in Phase 1 studies and in a small Phase 2 study of women with breast cancer. We are currently studying (Z)-endoxifen in three Phase 2 studies: one in healthy women with measurable breast density and two other studies including the EVANGELINE study in women with ER+/HER2- breast cancer. Atossa's (Z)-endoxifen is protected by three issued U.S. patents and numerous pending patent applications.

About Atossa Therapeutics
Atossa Therapeutics, Inc. is a clinical-stage biopharmaceutical company developing innovative medicines in areas of significant unmet medical need in oncology with a focus on breast cancer. For more information, please visit www.atossatherapeutics.com.

CONTACT:
Eric Van Zanten
VP, Investor and Public Relations
610-529-6219
eric.vanzanten@atossainc.com

FORWARD LOOKING STATEMENTS
Forward-looking statements in this press release, which Atossa undertakes no obligation to update, are subject to risks and uncertainties that may cause actual results to differ materially from the anticipated or estimated future results, including the risks and uncertainties associated with any variation between interim and final clinical results, actions and inactions by the FDA, the outcome or timing of regulatory approvals needed by Atossa including those needed to commence studies of (Z)-endoxifen, lower than anticipated rate of patient enrollment, estimated market size of drugs under development, the safety and efficacy of Atossa's products, performance of clinical research organizations and investigators, obstacles resulting from proprietary rights held by others such as patent rights, whether reduction in breast density or in Ki-67 or any other result from a neoadjuvant study is an approvable endpoint for (Z)-endoxifen, whether Atossa can complete acquisitions, and other risks detailed from time to time in Atossa's filings with the Securities and Exchange Commission, including without limitation its periodic reports on Form 10-K and 10-Q, each as amended and supplemented from time to time.