Atossa Therapeutics Announces First Patient Dosing of (Z)-Endoxifen in the Ongoing RECAST DCIS Study

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SEATTLE, Feb. 22, 2024 (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 announced that the first patient has been dosed with Atossa's proprietary Selective Estrogen Receptor Modulator (SERM), (Z)-endoxifen, in the Re-Evaluating Conditions for Active Surveillance Suitability as Treatment: Ductal Carcinoma In Situ (RECAST DCIS) study. RECAST DCIS is an ongoing Phase 2 platform study designed to offer women diagnosed with DCIS six months of neoadjuvant endocrine therapy with the intent of determining their suitability for long-term active surveillance without surgery.

A short 'explainer' video about Ductal Carcinoma In Situ and the RECAST DCIS study can be found here: DCIS Video Explainer.

"Ductal Carcinoma In Situ is pre-invasive cancer, but the current standard of care is to treat it like early-stage invasive breast cancer, which for most patients involves surgery, followed by radiation treatment for three to four weeks and finally hormone therapy for five years," Dr. Steven Quay, Atossa's President and Chief Executive Officer. "This is an overly aggressive treatment approach, especially when you consider most DCIS cases will not progress to invasive breast cancer if left untreated. We feel treatment with (Z)-endoxifen has the potential to replace the current standard of care, which would spare a significant percentage of patients diagnosed with DCIS from undergoing aggressive, invasive, unnecessary treatment."

The RECAST DCIS trial is sponsored and operated by Quantum Leap Healthcare Collaborative, which was established in 2005 as a collaboration between medical researchers at University of California, San Francisco and Silicon Valley entrepreneurs. Participants in the study will be treated with up to six months of endocrine therapy with the intent to forego surgery and instead be monitored via long-term active surveillance. A key element in reducing overtreatment of DCIS is identifying biomarkers that reflect the risk of progression so that those with low-risk lesions are spared surgery. RECAST DCIS features the assessment of imaging and molecular-based biomarkers in addition to evaluating new investigational agents in this setting. The (Z)-endoxifen study arm is expected to enroll up to 110 patients.

About Ductal Carcinoma In Situ
Ductal Carcinoma In Situ (DCIS) is considered the earliest form of breast cancer. DCIS is usually found during a mammogram done as part of breast cancer screening or to investigate a breast lump. It is noninvasive, meaning it hasn't spread out of the milk duct, and has a low risk of becoming invasive. Current standard of care includes surgery, radiation therapy, and/or hormone therapy. Approximately 60,000 DCIS diagnoses are made each year in the United States alone. Studies show that recurrence of DCIS can occur in up to 1 in 3 patients following treatment.

About (Z)-Endoxifen
(Z)-endoxifen is the most active metabolite of the FDA approved Selective Estrogen Receptor Modulator (SERM), tamoxifen. Studies 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. (Z)-endoxifen also appears to deliver similar or even greater bone agonistic effects while resulting in little or no endometrial proliferative effects compared with tamoxifen.

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. (Z)-endoxifen is currently being studied in four Phase 2 trials: one in healthy women with measurable breast density, one in women diagnosed with ductal carcinoma in situ, 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 Quantum Leap Healthcare Collaborative
Quantum Leap Healthcare Collaborative is a 501c(3) charitable organization established in 2005 as a collaboration between medical researchers at University of California, San Francisco and Silicon Valley entrepreneurs. Our mission is to integrate care and research, and to foster high-impact trials with embedded clinical processes and systems technology and improved data management, greater access to clinical trial matching, and greater benefit to patients, providers, and researchers. Our goal is to improve and save lives. Quantum Leap provides operational, financial, and regulatory oversight to I-SPY. For more information, visit https://www.quantumleaphealth.org/

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

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FORWARD LOOKING STATEMENTS
This press release contains certain information that may constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. We may identify these forward-looking statements by the use of words such as "expect," "potential," "continue," "may," "will,"

“should,” “could,” “would,” “seek,” “intend,” “plan,” “estimate,” “anticipate,” “believe,” “future,” or other comparable words. Forward-looking statements in this press release are subject to risks and uncertainties that may cause actual results, outcomes, or the timing of actual results or outcomes, to differ materially from those projected or anticipated, including risks and uncertainties associated with: macroeconomic conditions and increasing geopolitical instability; the expected timing of releasing data; any variation between interim and final clinical results; actions and inactions by the FDA and foreign regulatory bodies; the outcome or timing of regulatory approvals needed by Atossa, including those needed to continue our planned (Z)-endoxifen trials; our ability to satisfy regulatory requirements; our ability to regain compliance with the continued listing requirements of the Nasdaq Stock Market; our ability to successfully develop and commercialize new therapeutics; the success, costs and timing of our development activities, including our ability to successfully initiate or complete our clinical trials, including our (Z)-endoxifen trials; our anticipated rate of patient enrollment; our ability to contract with third-parties and their ability to perform adequately; our estimates on the size and characteristics of our potential markets; our ability to successfully defend litigation and other similar complaints and to establish and maintain intellectual property rights covering our products; whether we can successfully complete our clinical trial of oral (Z)-endoxifen in women with mammographic breast density and our trials of (Z)-endoxifen in women with breast cancer, and whether the studies will meet their objectives; our expectations as to future financial performance, expense levels and capital sources, including our ability to raise capital; our ability to attract and retain key personnel; our anticipated working capital needs and expectations around the sufficiency of our cash reserves; and other risks and uncertainties detailed from time to time in Atossa’s filings with the Securities and Exchange Commission, including without limitation its Annual Reports on Form 10-K and Quarterly Reports on 10-Q. Forward-looking statements are presented as of the date of this press release. Except as required by law, we do not intend to update any forward-looking statements, whether as a result of new information, future events or circumstances or otherwise.