Atossa Therapeutics and Quantum Leap Healthcare Provide Enrollment Update for (Z)-Endoxifen Arm of Ongoing I-SPY 2 Clinical Trial

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SEATTLE and SAN FRANCISCO, June 28, 2023 (GLOBE NEWSWIRE) -- Atossa Therapeutics, Inc. (Nasdaq: ATOS), a clinical stage biopharmaceutical company developing innovative medicines in areas of significant unmet medical need in oncology with a focus on breast cancer, and Quantum Leap Healthcare Collaborative™ ("Quantum Leap") today announced that six patients have been dosed with Atossa's proprietary Selective Estrogen Receptor Modulator (SERM), (Z)-endoxifen, in the ongoing Phase 2 I-SPY 2 clinical trial. (Z)-endoxifen is being evaluated as a neoadjuvant treatment for patients with newly diagnosed estrogen receptor-positive (ER+) invasive breast cancer whose tumors are predicted to be sensitive to endocrine therapy but for whom chemotherapy is expected to provide little or no benefit.

The I-SPY 2 TRIAL is a collaborative effort among academic investigators from major cancer research centers across the United States, Quantum Leap Healthcare Collaborative, the U.S. Food and Drug Administration, and the Foundation for the National Institutes of Health (FNIH) Cancer Biomarkers Consortium. The (Z)-endoxifen treatment arm, which is expected to enroll approximately 20 patients, is part of the I-SPY 2 Endocrine Optimization Pilot Protocol (EOP). Patients will receive 10 mg of (Z)-endoxifen daily for up to 24 weeks prior to surgery. Currently, there are 41 I-SPY 2 sites, all of which have the EOP program open.

"Reaching 30% enrollment in the I-SPY 2 study is another important milestone in our ambitious (Z)-endoxifen development program," said Dr. Steven Quay, Atossa's President and Chief Executive Officer. "These patients have substantial risk for recurrence and need novel treatment options that are more tolerable and more efficacious than currently approved drugs. (Z)-endoxifen has the potential to slow the progression of ER-positive breast cancer in the neoadjuvant setting, making surgery more effective and reducing the risk of recurrence. We look forward to seeing data from this trial, which along with data from our Phase 2 EVANGELINE trial, will inform conversations with the FDA and our planned Phase 3 protocol."

"With the ISPY 2.2 TRIAL, we have focused on optimizing treatments for the fast-growing breast cancers; that focus has allowed us to make great progress. But one of the biggest challenges in breast cancer is the hormone positive breast cancers that are slow growing. They can recur for up to 15 years or more, and we urgently need to find predictors of response so that we can prevent late recurrence. And we know that women suffer from the side effects of years of extended endocrine therapy, especially when they have larger tumors. So, we have a great need to find more effective and more tolerable agents so that women will live longer and better. The goal of the endocrine optimization pilot is to test these new and exciting hormone directed therapies like endoxifen," said Dr. Laura Esserman of the University of California San Francisco, founder and leader of the I-SPY TRIAL.

About Premenopausal Patients with ER+ / HER2- Breast Cancer
Breast cancer is the most frequently diagnosed cancer in premenopausal women worldwide and accounts for almost half of the cancers that occur in women aged 15-49. An overwhelming majority (75%) of premenopausal breast cancer falls under luminal A (ER+/HER2-) or B (ER+/HER2+) subtypes. Ovarian function suppression, when combined with either tamoxifen or an aromatase inhibitor, is the standard of care for the endocrine management of stage 2 and 3 premenopausal ER+/HER2- breast cancer. The I SPY Endocrine Optimization Pilot (EOP) specifically targets women of all ages with molecularly low risk stage 2 and 3 breast cancer.

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. The Company is 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

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 the I-SPY TRIALs
The I-SPY TRIAL (Investigation of Serial studies to Predict Your Therapeutic Response with Imaging And moLecular analysis 2) (I-SPY 2 TRIAL) was designed to rapidly screen promising experimental treatments and identify those most effective in specific patient subgroups based on molecular characteristics (biomarker signatures). The Endocrine Optimization Pilot (EOP) is developing better endpoints and new endocrine targeted agents for stage 2/3 molecularly low risk breast cancer. The trial is a unique collaborative effort by a consortium that includes the Food and Drug Administration (FDA), industry, patient advocates, philanthropic sponsors, and clinicians from 30 major U.S. cancer research centers. Under the terms of the collaboration agreement, Quantum Leap Healthcare Collaborative is the trial sponsor and manages all study operations. For more information, visit www.ispytrials.org.

Atossa Therapeutics Contact:
Eric Van Zanten

VP, Investor and Public Relations
610-529-6219
eric.vanzanten@atossainc.com

Quantum Leap Healthcare Collaborative Media Contact:
Jacqueline Murray
Director, Marketing and Communications
(415) 839-8082
j.murray@quantumleaphealth.org

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.