Atossa Therapeutics Announces Full Enrollment of (Z)-Endoxifen Arm of I-SPY 2 Clinical Trial

February 7, 2024 1:30 PM EST

SEATTLE, Feb. 07, 2024 (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, today announced that the (Z)-endoxifen arm of the ongoing Phase 2 I-SPY 2 clinical trial has fully enrolled. In the study, (Z)-endoxifen, Atossa's proprietary Selective Estrogen Receptor Modulator (SERM), is being evaluated as a neoadjuvant treatment for newly diagnosed estrogen receptor-positive (ER+) invasive breast cancer.

"We are excited that the (Z)-endoxifen arm of the I-SPY 2 study has fully enrolled and look forward to seeing data from this study in the second half of 2024," said Steven Quay, MD, PhD, Atossa's President and Chief Executive Officer. "Estrogen receptor positive breast cancer accounts for over 80% of all breast cancer diagnoses and unfortunately, the current neoadjuvant treatment options for these patients are sub-optimal. Treatment with (Z)-endoxifen has the potential to down-stage the tumor, improve tumor resectability and reduce the incidence of breast cancer recurrence, all while demonstrating a far superior safety and tolerability profile compared to aromatase inhibitors and systemic chemotherapy. This would transform the treatment paradigm for the hundreds of thousands of women diagnosed with ER-positive breast cancer every year."

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 enrolled 20 patients, is part of the I-SPY 2 Endocrine Optimization Pilot Protocol (EOP). Patients receive 10 mg of (Z)-endoxifen daily for up to 24 weeks prior to surgery.

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. (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 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

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.