Atossa Therapeutics Releases Promising Preliminary Analysis Demonstrating (Z)-Endoxifen's Potential to Rapidly Reduce Ki-67 and Tumor Volume in ER+/HER2- Breast Cancer

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(Z)-endoxifen at 10 mg once daily met the primary endpoint with 19/20 (95%) receiving > 75 % of planned treatment in I-SPY-2 Phase 2 Trial

Low dose (Z)-endoxifen was well tolerated and demonstrated promising rapid activity in reducing 3-wk Ki-67 and FTV Biomarkers

SEATTLE, Oct. 31, 2024 (GLOBE NEWSWIRE) -- Atossa Therapeutics, Inc. (Nasdaq: ATOS) ("Atossa" or the "Company"), today released a preliminary analysis from a phase 2 trial of (Z)-endoxifen as part of the I-SPY 2 Endocrine Optimization Pilot (EOP) will be the subject of a poster presentation at the inaugural RISE UP (**R**evolutionizing **I**nvestigations to **S**t**E**p **U**p **P**revention) Breast Cancer Conference in San Francisco, November 1-3, 2024. Atossa Therapeutics is a clinical-stage biopharmaceutical company developing innovative medicines for breast cancer. An explainer video of this announcement can be found here.

A preliminary data analysis from this study, which included 20 women with ER+/HER2- breast cancer who received 10mg of (Z)-endoxifen orally once daily for six cycles (each cycle = 28 days), showed that (Z)-endoxifen met the primary endpoint with 95 percent (19/20 patients) receiving > 75 % of planned treatment.

The data also demonstrated (Z)-endoxifen activity in rapidly reducing key biomarkers such as Ki-67 by 69 percent from baseline and a 30.4 percent reduction in functional tumor volume (FTV) from baseline after 3 weeks of treatment. Ki-67 is a protein that helps measure how quickly cancer cells in a tumor are dividing, and FTV is a quantitative measurement of tumor burden that can be used to assess treatment response for breast cancer.

(Z)-endoxifen was well tolerated in this study with the most common side effects being mild, including hot flushes, insomnia, and fatigue. No dose reductions or discontinuations due to treatment related adverse events were observed in this study. Surgical Ki-67 values and 24-wk imaging will be analyzed in the future.

"We are very encouraged by these results and thrilled by the signs of rapid reduction in Ki-67 and FTV as it demonstrates progress in our effort to develop (Z)-endoxifen as an effective and tolerant neoadjuvant treatment for ER+/HER2- breast cancer patients. This data provides further evidence that (Z)-endoxifen may be able to slow the progression of ER+ breast cancer in the neoadjuvant setting," said Dr. Steven Quay, Chief Executive Officer of Atossa Therapeutics. "We are honored to have these findings from the I-SPY 2 EOP study of (Z)-endoxifen presented at the inaugural RISE UP conference and commend Dr. Laura Esserman and other members of the Organizing Committee for their focus on reimagining breast cancer prevention and treatment."

The I-SPY 2 EOP trial focuses on 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. These patients have substantial risk for recurrence, often after five years, and need novel treatments that are more effective and tolerable than the current standard of care.

The ongoing study arm enrolled 20 women between March 2023 and May 2024. Participants received 10 mg of (Z)-endoxifen daily for six cycles, with ovarian function suppression introduced in premenopausal patients starting on cycle two. Primary endpoints included the feasibility of treatment, with >75 percent of patients completing the therapy. Secondary endpoints include changes in Ki-67 and FTV, both of which have demonstrated early reduction in response to (Z)-endoxifen. Higher doses of (Z)-endoxifen in combination with abemaciclib are currently being explored in ongoing studies to further enhance the dual targeting of ERα and PKCβ activity.

About (Z)-Endoxifen
(Z)-endoxifen is one of the most potent Selective Estrogen Receptor Modulator (SERM) for estrogen receptor inhibition and may cause estrogen receptor degradation. It has also been shown to have efficacy in the setting of patients with tumor resistance to other hormonal treatments. In addition to its potent anti-estrogen effects, (Z)-endoxifen has been shown to target PKCβ1, a known oncogenic protein, at clinically attainable blood concentrations. Finally, (Z)-endoxifen appears to deliver similar or even greater bone agonistic effects while resulting in little or no endometrial proliferative effects compared with standard treatments, like tamoxifen.

Atossa is developing a proprietary oral formulation of (Z)-endoxifen that is encapsulated to bypass the stomach, as acidic conditions in the stomach convert a significant 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 five phase 2 trials: one in healthy women with measurable breast density, one in women diagnosed with ductal carcinoma in situ, and three other studies including the EVANGELINE study and two I-SPY studies in women with ER+/HER2- breast cancer. Atossa's (Z)-endoxifen is protected by four 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 using (Z)-endoxifen to prevent and treat 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, such as data related to the (Z)-endoxifen program, the potential of (Z)-endoxifen as a breast cancer prevention and treatment agent, and potential milestones and growth opportunities for the Company, 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 remain compliant 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.