Atossa Therapeutics Completes Enrollment of 80mg Pharmacokinetic Run-In Cohort in Phase 2 EVANGELINE Clinical Trial Evaluating (Z)-Endoxifen as a Neoadjuvant Treatment for ER+ / HER2- Breast Cancer

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SEATTLE, July 22, 2024 (GLOBE NEWSWIRE) -- Atossa Therapeutics, Inc. (Nasdaq: ATOS) ("Atossa" or the "Company") today announced that the 12-patient 80mg pharmacokinetic (PK) run-in cohort of the Phase 2 EVANGELINE (Endoxifen Versus exemestANe GosEreLIn) study has fully enrolled. EVANGELINE is a randomized non-inferiority trial of Atossa's patented Selective Estrogen Receptor Modulator (SERM), (Z)-endoxifen, and exemestane plus goserelin as a neoadjuvant treatment for pre-menopausal women with Grade 1 or 2 Estrogen Receptor positive (ER+) / Human Epidermal Growth Factor Receptor 2 negative (HER2-) breast cancer. Atossa is a clinical stage biopharmaceutical company developing innovative medicines in areas of significant unmet medical need in oncology with a focus on breast cancer.

The 80mg PK run-in cohort consists of 12 pre-menopausal women, all of whom will be treated with (Z)-endoxifen at 80mg/day for four weeks. After four weeks of treatment, participants with Ki-67 levels below 10% will continue on study drug for five additional months, followed by surgery. Ki-67 is a cellular marker for proliferation that indicates how fast the tumor is growing. Once the optimal dose of (Z)-endoxifen is determined, the treatment cohort will commence. The study is expected to enroll approximately 175 patients at up to 25 sites across the United States.

The EVANGELINE study began with a 40mg PK run-in cohort. Data from this cohort, which was presented at the 2024 American Association for Cancer Research (AACR) Annual Meeting, showed encouraging efficacy and an extremely favorable safety profile compared to currently approved endocrine therapies. Participants treated for a total of 24-weeks experienced an average reduction in Ki-67 of 92% and an average target lesion decrease of 37%. MRI central review at week 12 and week 24 demonstrated tumor shrinkage in all patients with one complete response, one partial response and four cases of stable disease. The 80mg dose is expected to deliver the optimal drug concentrations required to fully target PKCβ1 inhibition and further enhance (Z)-endoxifen's antitumor efficacy.

"Full enrollment of the 80mg pharmacokinetic run-in cohort of the EVANGELINE study is yet another important milestone in our ambitious (Z)-endoxifen development program," said Steven Quay, M.D., Ph.D., Atossa's President and Chief Executive Officer. "Based on data from the 40mg cohort and a review of safety, efficacy and PK data from participants enrolled earlier in the 80mg PK run-in cohort, we are confident that the 80mg dose will be well tolerated and deliver the optimal concentration levels to fully target PKCβ1 inhibition. We look forward to opening the treatment arm of this important study and bringing this potentially transformative treatment to women diagnosed with breast cancer as quickly as possible."

About the Phase 2 EVANGELINE Study
The Phase 2 EVANGELINE (Endoxifen Versus exemestANe GosEreLIn) study is a randomized non-inferiority trial of Atossa's patented Selective Estrogen Receptor Modulator (SERM), (Z)-endoxifen, and exemestane plus goserelin as a neoadjuvant treatment for pre-menopausal women with Grade 1 or 2 Estrogen Receptor positive (ER+) / Human Epidermal Growth Factor Receptor 2 negative (HER2-) breast cancer. The primary objective of the EVANGELINE study is to evaluate the endocrine sensitive disease (ESD) rate, measured by Ki-67 (a proliferation marker prognostic for disease free survival), after four weeks of treatment with (Z)-endoxifen compared to treatment with current standard of care, exemestane plus goserelin. Exemestane is an aromatase inhibitor designed to block the synthesis of estrogen and slow the growth of ER+ cancers. Goserelin is a medication given to block the ovaries from making estrogen, also called ovarian function suppression (OFS). In premenopausal women, OFS is associated with significant morbidity and inadequate compliance, which compromises efficacy and increases the risk of mortality.

About (Z)-Endoxifen
(Z)-endoxifen is the most potent Selective Estrogen Receptor Modulator (SERM) for estrogen receptor inhibition and also causes 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 does not require liver metabolism to achieve therapeutic concentrations and 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 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 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, including the timing of data related to the (Z)-endoxifen program, the potential of (Z)-endoxifen as a breast cancer prevention and treatment agent, and the potential safety and tolerability profile of (Z)-endoxifen, 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 comply 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.