Atossa to Present a Trial in Progress Poster on its Neoadjuvant Breast Cancer Phase 2 Clinical Trial, EVANGELINE, at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting

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SEATTLE, May 09, 2023 (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 current focus on breast cancer, today announces that a Trial in Progress poster for the Phase 2 clinical study of (Z)-endoxifen in premenopausal women with early stage ER+ / HER2- breast cancer will be presented at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting, taking place June 2-6, 2023 in Chicago.

"We're excited to present an overview of our ongoing Phase 2 study, EVANGELINE, at the 2023 ASCO annual meeting," said Dr. Steven Quay, Atossa's President and Chief Executive Officer. "The EVANGELINE study is one of two ongoing Phase 2 trials investigating our proprietary (Z)-endoxifen as a neoadjuvant treatment for women with estrogen receptor positive breast cancer. We look forward to sharing more about this novel compound as we further our work to address unmet clinical needs across the continuum of breast cancer prevention and treatment."

Details of the presentation are:

- **Abstract:** TPS633 **Poster Bd#** 454a
- **Abstract Title:** A randomized phase 2 non-inferiority trial of (Z)-endoxifen and exemestane + goserelin as neoadjuvant treatment for premenopausal women with ER+/HER2- breast cancer (EVANGELINE)
- **Session Title:** Breast Cancer—Local/Regional/Adjuvant
- **Session Date and Time:** Sunday, June 4, 2023, 8:00 AM-11:00 AM CT
- **Presenter:** Matthew P. Goetz, MD | Mayo Clinic

The full abstract will become public at 5:00 pm ET on Thursday, May 25, 2023.

About EVANGELINE
EVANGELINE (Endoxifen Versus exemestANe GosEreLIn, NCT05607004) is a randomized non-inferiority study of (Z)-endoxifen compared to exemestane plus goserelin as a neoadjuvant treatment for premenopausal women with Grade 1 or 2 ER+ / HER2- breast cancer. Participants receive neoadjuvant treatment for up to six months, followed by surgery. The primary objective of the EVANGELINE study is to determine whether 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 is non-inferior to the ESD rate following 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, which in premenopausal women is associated with significant morbidity and inadequate compliance, which compromises efficacy and increases the risk of mortality.

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.

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. We are 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 two 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 current focus on breast cancer. For more information, please visit www.atossatherapeutics.com

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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.