Data from Atossa's Phase 2 EVANGELINE Clinical Trial to be Presented at American Association for Cancer Research (AACR) Annual Meeting

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SEATTLE, March 06, 2024 (GLOBE NEWSWIRE) -- Atossa Therapeutics, Inc. (Nasdaq: ATOS) announced today that data from the 40mg pharmacokinetic (PK) run-in cohort of the ongoing Phase 2 EVANGELINE (Endoxifen Versus exemestANe GosEreLIn) study will be presented at the American Association for Cancer Research (AACR) Annual Meeting, taking place April 5-10, 2024, in San Diego, California. The EVANGELINE study is investigating (Z)-endoxifen as a neoadjuvant treatment for premenopausal women diagnosed with 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.

"We're excited that the EVANGELINE data from the 40 mg cohort of patients was accepted for presentation at the 2024 American Association for Cancer Research Annual Meeting," said Dr. Steven Quay, Atossa's President and Chief Executive Officer. "While neoadjuvant therapy is effective and widely used across many cancer types, the current treatment options for premenopausal women diagnosed with ER+ breast cancer are sub-optimal. An effective and tolerable neoadjuvant therapy would transform the treatment approach in this setting, making surgery more effective and reducing the likelihood that the cancer will recur. There is growing excitement and understanding across the breast cancer community that (Z)-endoxifen, if shown to be safe and effective, would be a game changer for premenopausal women."

Details of the presentation are:

- **Session Title:** Phase II Clinical Trials 1
- **Abstract Title:** Neoadjuvant (Z)-endoxifen in premenopausal ER+, HER2- breast cancer: Evaluation of the first pharmacokinetic cohort of the EVANGELINE trial
- **Session Date and Time:** Tuesday April 9, 2024 – 9:00 AM - 12:30 PM
- **Abstract Presentation Number:** CT205

The full abstract text will be posted to the AACR online itinerary planner and meeting app at 3:00 pm ET on Friday, April 5, 2024.

Organized by the American Association for Cancer Research, the AACR Annual Meeting is the largest and most important cancer drug discovery event in the world. It has an anticipated attendance of more than 20,000 scientists, clinicians, advocates, and other attendees. The event spans integrative cancer science, global impact, individualized patient care, and showcases the best and most up-to-date cancer science available.

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 current 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 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. (Z)-endoxifen also appears to deliver similar or even greater bone agonistic effects while resulting in little or no endometrial proliferative effects compared with 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 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 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

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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. All statements other than statements of historical fact, including statements regarding the timing of data related to the (Z)-endoxifen program, the potential of (Z)-endoxifen as a breast cancer prevention and treatment agent, guidance, industry prospects, or future results of operations or financial position made in this press release are forward-looking. 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.