Atossa Therapeutics Announces Five Abstracts Highlighting (Z)-Endoxifen Research Accepted for Presentation at the 2024 San Antonio Breast Cancer Symposium

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Detailed results from the KARISMA-Endoxifen trial demonstrating (Z)-endoxifen's ability to significantly reduce mammographic breast density to be featured at conference

SEATTLE, Nov. 20, 2024 (GLOBE NEWSWIRE) -- Atossa Therapeutics, Inc. (Nasdaq: ATOS) ("Atossa" or the "Company"), 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 five abstracts featuring data on (Z)-endoxifen have been accepted for presentation at the San Antonio Breast Cancer Symposium (SABCS), taking place December 10-13, 2024, in San Antonio, Texas.

The presentations will showcase significant findings from various studies evaluating the use of (Z)-endoxifen in breast cancer prevention and treatment, including phase 2 trials and innovative combination therapy research.

"We are excited to present a comprehensive body of research on (Z)-endoxifen at SABCS 2024," said Dr. Steven Quay, President and Chief Executive Officer of Atossa Therapeutics. "These presentations highlight our commitment to advancing breast cancer treatment and prevention, showcasing the potential of (Z)-endoxifen to bring meaningful treatment options to patients with breast cancer."

Abstract Highlights and Presentation Details:
Poster Spotlight Session 16
Title: PS16-05 Primary Breast Cancer Prevention Using Oral Endoxifen

- **Description**: Evaluates the effectiveness of low-dose (Z)-endoxifen in reducing mammographic breast density, a significant risk factor for breast cancer.
- **Poster Details**: Per Hall, Karolinska Institutet, 5:30-6:00 pm, Thursday, December 12

Title: P2-03-07 Neoadjuvant Z-endoxifen for Premenopausal Estrogen Receptor (ER)+, Human Epidermal Receptor (HER2)- Breast Cancer (BC): Evaluation of Quality of Life (QOL) measures in the EVANGELINE Study:

- **Description**: Reports on quality of life outcomes, menopausal symptoms, and patient-reported experiences of (Z)-endoxifen treatment in premenopausal women with ER+/HER2- breast cancer.
- **Presentation Details**: Sarah Premji, 5:30-7:00 pm, December 11, 2024

Title: P1-11-04 Neoadjuvant Z-endoxifen for Premenopausal Estrogen Receptor (ER)+, Human Epidermal Growth Factor Receptor (HER2)- Breast Cancer (BC): Evaluation of the Pharmacokinetic (PK) Run-in for the EVANGELINE Study:

- **Description**: Details the PK profile and optimal dosing strategy of (Z)-endoxifen, highlighting its efficacy and tolerable safety profile.
- **Presentation Details**: Matthew Goetz, 12:30-2:00 pm, December 11, 2024

Title: P4-05-22 Discovery of Molecules Synergistic with (Z)-endoxifen for the Treatment of Breast Cancer

- **Description**: Presents findings from a study exploring synergistic combinations of (Z)-endoxifen with other compounds for enhanced treatment efficacy.
- **Presentation Details:** Daniela Huhn, 5:30-7:00 pm, December 13, 2024

Title: P2-12-18 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)

- **Description**: Examines the non-inferiority of (Z)-endoxifen compared to exemestane plus goserelin in premenopausal women with ER+/HER2- breast cancer, focusing on reducing the need for ovarian function suppression.
- **Presentation Details**: Matthew Goetz, 5:30-7:00 pm, December 11, 2024

For additional information, please visit the SABCS website: https://sabcs.org.

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 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.

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.

Contact:

Michael Parks
VP, Investor and Public Relations
484-356-7105
michael.parks@atossainc.com