Atossa Therapeutics Presents Data from Study Investigating Anti-Cancer Activity of (Z)-Endoxifen-Related Compounds at AACR Special Conference in Cancer Research

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Novel Compounds Demonstrate Promising Anti-Tumor Activity in Estrogen Receptor-Positive (ERα+) Breast Cancer, Including Endocrine-Resistant Tumors

SEATTLE, Dec. 09, 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 the presentation of research investigating the anti-cancer activity of (Z)-endoxifen and its byproducts at the American Association for Cancer Research (AACR) Special Conference in Cancer Research, taking place in Toronto from December 9-11.

The poster, titled, "Anti-cancer activity of (Z)-endoxifen-related compounds in ERα+ breast cancer," outlines results from a study investigating four (Z)-endoxifen byproducts for their anti-estrogenic and anti-tumor effects in estrogen receptor-positive (ERα+) breast cancer cell lines, including those with ESR1 mutations (Y537S and D538G) associated with endocrine resistance. Notably, compounds AT416E and AT402E demonstrated strong anti-proliferative activity, with AT416E also showing enhanced inhibition of cell migration and invasion. All four byproducts exhibited greater anti-proliferative effects than (Z)-endoxifen in estrogen-deficient conditions, while (Z)-endoxifen remained the most potent at inducing cell cycle arrest and apoptosis, reinforcing its potential as a therapeutic agent.

"These findings highlight the therapeutic potential of (Z)-endoxifen and its byproducts in addressing ER+ breast cancers, including those resistant to current endocrine therapies, which represent a significant challenge for patients," said Steven Quay, M.D., Ph.D., Atossa's President and Chief Executive Officer. "The ability of these compounds to inhibit key cancer mechanisms positions them as promising, targeted candidates for future therapeutic development aimed at expanding treatment options for this difficult-to-treat population."

Building on these findings, future *in vivo* studies are planned to validate the potential of (Z)-endoxifen byproducts to overcome the limitations of existing endocrine therapies and to explore their clinical application in developing new treatment strategies for estrogen receptor-positive breast cancer.

Poster Details

Title: Anti-cancer activity of (Z)-endoxifen-related compounds in ERα+ breast cancer

- **Description** Explores the optimization of therapeutic efficacy and tolerability through modifications to (Z)-endoxifen chemistry.
- **Time/Place** Tuesday, December 10, 2024
  6:30-8:00 pm ET.

For additional information, please visit the conference website here.

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.

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," "design," "predict," "future," or other comparable words. All statements made in this press release that are not statements of historical fact, including statements regarding data related to the (Z)-endoxifen program, the potential of (Z)-endoxifen as a breast cancer prevention and treatment agent, the expected timing of data and related publications, and the potential milestones and growth opportunities for the Company, are forward-looking statements. 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 or preliminary and final clinical results or analysis; 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.

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