Atossa Therapeutics Commemorates Breast Cancer Awareness Month, Highlighting the Need for Innovation Across the Breast Cancer Treatment Continuum

October 1, 2024 12:30 PM EDT

SEATTLE, Oct. 01, 2024 (GLOBE NEWSWIRE) -- Atossa Therapeutics, Inc. (Nasdaq: ATOS) ("Atossa" or the "Company"), today announced its recognition and support of Breast Cancer Awareness Month this October; highlighting the importance of increasing awareness, advancing research, and driving progress toward innovative treatments for breast cancer. Approximately one in eight women will be diagnosed with breast cancer in their lifetime, so this annual campaign serves as a powerful reminder of the ongoing need for education, early detection, prevention, and access to effective treatment options. Atossa Therapeutics is a clinical-stage biopharmaceutical company developing innovative medicines for breast cancer.

This year's Breast Cancer Awareness Month takes on added significance with the recent implementation of the U.S. Food and Drug Administration's (FDA) updated rule under the Mammography Quality Standards Act (MQSA). The new rule, which became effective on September 10, 2024, requires healthcare providers to notify women of their breast density results following a mammogram. Dense breast tissue is a known risk factor for breast cancer, and women with this condition are encouraged to consult with their healthcare providers about additional screening options to ensure earlier detection.

"As we honor Breast Cancer Awareness Month, it's essential to reflect on the importance of education and early detection in the fight against breast cancer," said Steven Quay, M.D., Ph.D., Atossa's President and Chief Executive Officer. "While significant progress has been made, continued research is critical to improve outcomes for the millions of women impacted by breast cancer every year. At Atossa, we are dedicated to advancing innovative treatments and increasing awareness of risk factors, such as dense breast tissue, that can contribute to missed diagnoses."

Atossa is currently evaluating its lead asset, (Z)-endoxifen, in multiple phase 2 clinical trials, including the Karisma-Endoxifen study, which is investigating the potential for (Z)-endoxifen to reduce mammographic breast density in premenopausal women with measurable density. Data from this trial is expected in the fourth quarter of 2024. Currently, there are no approved treatments available to reduce breast density, a condition that can obscure tumors during mammograms and increase the risk of undiagnosed cancer.

Atossa is also supporting the SMART (Stockholm MAmmography Risk stratified Trial) study, a recently announced phase 2 study designed to validate an innovative, artificial intelligence driven, breast cancer risk assessment model. The study will test an individualized, imaging-based screening model designed to identify women with the highest risk of developing breast cancer in the next two years. If the model is validated for therapeutic use, it could serve as the foundation for a future phase 3 trial investigating (Z)-endoxifen in the breast cancer prevention setting.

About (Z)-Endoxifen
(Z)-endoxifen is one of the most potent Selective Estrogen Receptor Modulators (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/tissue 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 five 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.

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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, 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.