Atossa Therapeutics Announces Support of Final Rule from FDA Requiring Patient Notification of Breast Density, a Critical Step in Addressing a Known Risk Factor for Breast Cancer

September 10, 2024 12:30 PM EDT

FDA Update to Mammography Regulations in MQSA Final Rule is Effective Today

SEATTLE, Sept. 10, 2024 (GLOBE NEWSWIRE) -- Atossa Therapeutics, Inc. (Nasdaq: ATOS) ("Atossa" or the "Company"), today announced its support of the U.S. Food and Drug Administration (FDA) for issuing a final rule to update the mammography regulations issued under the Mammography Quality Standards Act of 1992 (MQSA), which becomes effective today. Among the updates, the final rule requires mammography facilities to provide patients with an assessment of breast density in patient friendly terms. 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.

Implementation of the FDA's final rule marks a significant step forward in the ongoing effort to improve breast cancer detection and patient outcomes. Breast density is a known, independent risk factor for developing breast cancer and can obscure the detection of tumors during mammography. This regulation is expected to significantly improve early breast cancer detection by ensuring that women with dense breast tissue are notified, empowering them to have informed discussions with their healthcare providers about supplemental screening options such as ultrasound or MRI, which may detect cancers that mammograms might miss.

"The implementation of the breast density notification rule is commendable and paves the way for better detection and diagnosis," said Steven Quay, M.D., Ph.D., Atossa's President and Chief Executive Officer. "The new requirements lay the groundwork for guiding patients and physicians in managing dense breast tissue, especially concerning Estrogen Receptor-positive (ER+) breast cancers, where density plays a critical role in risk assessment."

Atossa recognizes the significance of this rule as it aligns with the Company's mission to advance the early detection and prevention of breast cancer. 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 the trial is expected prior to year-end 2024. Currently, there are no approved treatments to reduce breast density.

Atossa is also proudly 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 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/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.

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