Atossa Therapeutics Announces Support of New Breast Cancer Screening Guidelines

May 7, 2024 12:30 PM EDT

SEATTLE, May 07, 2024 (GLOBE NEWSWIRE) -- Atossa Therapeutics, Inc. (Nasdaq: ATOS) ("Atossa" or the "Company") today announced its support of new guidelines released by the U.S. Preventive Services Task Force (USPSTF) recommending that women begin breast cancer screening starting at age 40. 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.

The updated guidelines recommend women undergo biennial mammography screening beginning at the age of 40 until the age of 74. The change to the recommended age comes in response to rising breast cancer rates among younger women and racial disparities in breast cancer diagnosis and mortality. The announced changes from USPSTF also come in advance of a September 2024 deadline mandated by U.S. FDA requiring mammogram facilities to provide women with detailed information regarding their breast density, as part of routine mammograms. Breast density is a significant independent risk factor for the development of breast cancer and can also decrease the effectiveness of mammograms in detecting cancerous lesions. Atossa Therapeutics recognizes the significance of these improved guidelines in empowering both healthcare providers and patients to make informed decisions regarding breast cancer screening and treatment.

Atossa is currently evaluating its lead asset, (Z)-endoxifen, in five Phase 2 clinical trials. One of those trials, the Karisma-Endoxifen study, is investigating (Z)-endoxifen's ability to reduce mammographic breast density in premenopausal women with measurable density. The trial fully enrolled in November 2023 and data is expected in the second half of 2024. Currently, there are no approved treatments to reduce breast density.

"The new guidelines will undoubtedly improve timely access to patient care and save lives by enabling earlier diagnosis and treatment of breast cancer," said Steven Quay, M.D., Ph.D., Atossa's President and Chief Executive Officer. "However, a bigger opportunity to help women is by developing therapies to prevent breast cancer from ever occurring. Half the women in the world over the age of 40 have dense breast tissue and women with very dense breasts are five-times more likely to get breast cancer than women with fatty breasts. Reducing breast density would not only make mammograms more effective, but more importantly, it could significantly reduce the likelihood that these women ever develop breast cancer."

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 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 using (Z)-endoxifen to prevent and treat breast cancer. For more information, please visit www.atossatherapeutics.com.

Contact:
Eric Van Zanten
VP, Investor and Public Relations
610-529-6219
eric.vanzanten@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, including the timing of data related to the (Z)-endoxifen program, the potential of (Z)-endoxifen as a breast cancer prevention and treatment agent, and the potential safety and tolerability profile of (Z)-endoxifen, 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 comply 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.