



Atossa Therapeutics Announces Plans to Pursue Metastatic Breast Cancer Indication for (Z)-Endoxifen and Continued Engagement with FDA on Additional Indications

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SEATTLE, March 11, 2025 (GLOBE NEWSWIRE) -- [Atossa Therapeutics, Inc.](#) (Nasdaq: ATOS) ("Atossa" or the "Company"), a clinical-stage biopharmaceutical company dedicated to the prevention and treatment of breast cancer, today announced its strategic decision to pursue a metastatic breast cancer indication for (Z)-endoxifen. Atossa believes that pursuing a metastatic indication may offer a more efficient regulatory pathway to deliver (Z)-endoxifen to women in urgent need, and simultaneously plans to work with the FDA to advance additional indications, such as breast cancer prevention and neoadjuvant therapy, that often require larger and longer clinical trials.

Addressing the High Unmet Need in Metastatic Breast Cancer

Metastatic breast cancer remains a significant area of unmet medical need, with current treatment options often providing limited durability of response and substantial side effects. (Z)-endoxifen, a potent and well-tolerated selective estrogen receptor modulator (SERM), has shown encouraging signals in previous clinical trials, which we believe supports its potential to fill this critical gap in treatment.

Promising Data from Phase 1 and Phase 2 Trials

(Z)-endoxifen has shown encouraging results in early-stage trials, which we believe reinforces its potential as a transformative therapy for breast cancer. Key findings from early clinical programs include:

- **Significantly improved progression-free survival (PFS) in CDK4/6i-naïve patients:** (Z)-endoxifen more than doubled the median PFS compared to tamoxifen (7.2 vs. 2.4 months), highlighting its potency in an endocrine-sensitive population.
- **Substantial activity observed even after tamoxifen progression:** Patients in the crossover arm who progressed on tamoxifen and switched to (Z)-endoxifen experienced clinical benefit, including partial responses and prolonged stable disease exceeding 2-3 years in some cases.
- **Favorable safety profile:** Despite its higher potency, (Z)-endoxifen has not shown unexpected safety concerns beyond what is typically seen with tamoxifen and has been generally well-tolerated.

Dr. Steven Quay, Chairman and Chief Executive Officer of Atossa Therapeutics, stated: "Our decision to advance (Z)-endoxifen into a metastatic breast cancer indication underscores our unwavering commitment to developing a best-in-class therapy for women facing this devastating disease. The encouraging clinical data that has been generated to date supports the potential of (Z)-endoxifen to provide a meaningful benefit to patients who have exhausted other treatment options. By pursuing this strategy, we believe we are not only addressing an urgent medical need but also fortifying the path forward for expanding (Z)-endoxifen's role across the full spectrum of breast cancer prevention and treatment. We look forward to providing future updates as we execute this plan."

The Strategic Advantage of a Metastatic Indication

We believe that pursuing an initial approval in metastatic breast cancer provides an efficient regulatory and clinical path to market, potentially allowing Atossa to more rapidly bring (Z)-endoxifen to patients who need it most. This approach can also strengthen the foundation for the expansion of (Z)-endoxifen into earlier-stage disease settings, where (Z)-endoxifen has already shown significant promise in reducing tumor proliferation and preventing recurrence.

Advancing Additional Indications in Prevention and Early-Stage Disease

Beyond metastatic disease, Atossa remains committed to demonstrating the broad clinical utility of (Z)-endoxifen across the breast cancer treatment paradigm. Since the release of compelling data at the end of 2024, the Company is actively engaging with the FDA to further define a regulatory path forward for additional indications, including in:

- **Breast Cancer Prevention:** Prior studies have indicated that (Z)-endoxifen can significantly reduce breast tissue density and estrogen receptor activity, key risk factors for developing breast cancer.
- **Neoadjuvant Therapy:** Data from early-stage patients indicate that the 4-week Ki-67 $\leq 10\%$ response rate remained consistently above 85 percent across all dose levels, regardless of the presence of ovarian function. These findings suggest that (Z)-endoxifen may effectively reduce tumor proliferation, which may lead to improved surgical outcomes and long-term prognosis.

Atossa Therapeutics remains dedicated to accelerating the development of (Z)-endoxifen with the goal of helping patients across all stages of breast cancer to benefit from its therapeutic potential.

About Atossa Therapeutics

Atossa Therapeutics, Inc. (Nasdaq: ATOS) is a clinical-stage biopharmaceutical company dedicated to transforming breast cancer treatment through innovative science and patient-focused solutions. The company's lead product candidate, (Z)-endoxifen, is a highly potent SERM designed for use across the breast cancer spectrum, including prevention, neoadjuvant, adjuvant, and metastatic settings. Atossa is committed to advancing its robust clinical research programs to improve patient outcomes while creating sustainable value for shareholders. For more information, visit 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 safety, tolerability and efficacy of (Z)-endoxifen, the potential of (Z)-endoxifen as a breast cancer prevention and treatment agent, the potential indications that the Company may pursue for (Z)-endoxifen, the potential for (Z)-endoxifen to receive regulatory approval, benefits of the Company's strategy of pursuing a metastatic indication for (Z)-endoxifen, the expected design and enrollment of trials and timing of data and related publications, and the potential market 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: our ability to obtain patent coverage for our product candidates; 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 regain compliance or maintain compliance 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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