Atossa Therapeutics Announces Full Results from Phase 2 KARISMA-Endoxifen Study Demonstrating Statistically Significant Reductions in Mammographic Breast Density

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1 MG Dose (Z)-Endoxifen Shows Potential as a Well-Tolerated, Preventative Therapy for Premenopausal Women at Risk of Developing Breast Cancer

Data to be Presented in a Poster Spotlight Session During the 2024 San Antonio Breast Cancer Symposium

SEATTLE, Dec. 11, 2024 (GLOBE NEWSWIRE) -- Atossa Therapeutics, Inc. (Nasdaq: ATOS) ("Atossa" or the "Company"), today announced full results from its Phase 2 KARISMA-Endoxifen trial conducted at the Karolinska Institute in Stockholm, Sweden. The data, which will be presented during a Poster Spotlight Session at the 2024 San Antonio Breast Cancer Symposium, highlight the potential of low-dose (Z)-endoxifen to significantly reduce mammographic breast density (MBD), a key risk factor for breast cancer, while demonstrating a favorable safety profile. 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 randomized, double-blind, placebo-controlled study enrolled 240 premenopausal women aged 40-55, randomized to one of three arms: placebo, 1 mg, or 2 mg of daily oral (Z)-endoxifen for six months. The study aimed to evaluate reductions in MBD and assess safety and tolerability.

Results showed that the 1 mg dose of (Z)-endoxifen reduced MBD by 17.3 percentage points ($p<0.01$), while the 2 mg dose achieved a reduction of 23.5 percentage points ($p<0.01$), compared to a minimal change in the placebo group of 0.27 percentage points. Plasma concentrations for (Z)-endoxifen were measured at 4.8 ng/mL and 9.7 ng/mL for the 1 mg and 2 mg arms, respectively, highlighting the effectiveness of the lower dose in achieving significant reductions. Importantly, no significant differences in adverse events were observed between the 1 mg dose and placebo. The 2 mg dose was associated with higher rates of hot flashes, night sweats and vaginal discharge.

"These results underscore the promise of (Z)-endoxifen as a preventative therapy for women with dense breast tissue," said Steven Quay, M.D., Ph.D., Atossa's President and Chief Executive Officer. "The ability to achieve statistically significant reductions in mammographic breast density with a low dose of (Z)-endoxifen that also avoids toxicity issues common to tamoxifen suggests this therapy could be particularly suitable for premenopausal women and could represent an important breakthrough in breast cancer prevention."

Mammographic breast density, an independent risk factor for breast cancer, not only complicates tumor detection on mammograms, but is also associated with an increased likelihood of developing the disease. The KARISMA-Endoxifen trial results align with outcomes observed in prior studies using tamoxifen, demonstrating comparable reductions in MBD with lower plasma concentrations and fewer side effects, emphasizing the potential of (Z)-endoxifen as a safer and more targeted alternative.

Presentation Details:
Poster Spotlight Session 16
Title: PS16-05 Primary Breast Cancer Prevention Using Oral Endoxifen

- **Description**: Evaluates the effectiveness of low-dose (Z)-endoxifen in reducing mammographic breast density, a significant risk factor for breast cancer.
- **Poster Details**: Per Hall, Karolinska Institutet, 5:30-6:00 pm, Thursday, December 12

A link to the poster presentation will be made available on Atossa Therapeutics' website at the time of the presentation. For additional information, please visit the SABCS website: https://sabcs.org.

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 safety, tolerability and efficacy of (Z)-endoxifen, the potential of (Z)-endoxifen as a breast cancer prevention and treatment agent, the expected design and enrollment of trials and 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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