Atossa Therapeutics Further Strengthens Intellectual Property Portfolio with Additional Broad Patent for Endoxifen

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SEATTLE, Feb. 13, 2023 (GLOBE NEWSWIRE) -- Atossa Therapeutics, Inc. (Nasdaq: ATOS), a clinical stage biopharmaceutical company developing innovative proprietary medicines to address significant unmet need in cancer, today announces that the United States Patent and Trademark Office (USPTO) has granted a new patent (No. 11,572,334) directed to (Z)-endoxifen encapsulated in an enteric capsule. This patent further reinforces Atossa's broad Intellectual Property portfolio related to (Z)-endoxifen. A short 'explainer' video about the new patent can be found here: Patent Update - Video Explainer.

Enteric capsules have an acid resistant coating to prevent them from dissolving when they pass through the stomach. Enteric capsules are dissolved when they pass through an alkaline environment, which is usually when they reach the small intestine. Delivering oral (Z)-endoxifen via an enteric capsule prevents breakdown of the endoxifen in the stomach.

"We are very pleased with the scope and breadth of this new key patent," said Dr. Steven Quay, Atossa's President and Chief Executive Officer. "It ensures that in the U.S., Atossa will have the only (Z)-endoxifen treatment delivered orally with an enteric capsule, which we believe is the optimal way to deliver the drug. This new patent, further strengthens our intellectual property estate and should create long-term stockholder value."

Atossa is developing its proprietary (Z)-endoxifen in both the breast cancer treatment and prevention settings. Phase 2 trials are ongoing with the goal of changing the treatment paradigm for patients who are not benefiting from currently approved drugs and helping reduce the incidence of breast cancer.

- Phase 2 "EVANGELINE" study – (Z)-endoxifen and exemestane + goserelin as neoadjuvant treatment in premenopausal women with ER+/HER2- breast cancer. The EVANGELINE trial is expected to enroll approximately 175 patients at up to 25 sites across the United States and builds on an earlier Phase 2 study that showed treatment with (Z)-endoxifen reduced Ki-67, a commonly used measure of cellular proliferation and growth in breast cancer tissue. The EVANGELINE trial will evaluate safety and tolerability of treatment with (Z)-endoxifen, reduction in Ki-67 and pathological response. It will also study whether treatment with (Z)-endoxifen in premenopausal women could provide clinical benefit without the need for ovarian suppression.

- Phase 2 "Karisma-Endoxifen" study – (Z)-endoxifen in premenopausal women with elevated mammographic breast density (MBD). This randomized, double-blind, placebo-controlled trial of healthy, pre-menopausal women with increased breast density is expected to enroll 240 study participants. The treatment cohort receives daily doses of (Z)-endoxifen for six months, over the course of which mammograms will be conducted to measure reduction in MBD. Patients will also be given a mammogram at 24 months to assess the durability of the MBD changes.

Both trials seek to address significant unmet medical need in breast cancer. While there are several FDA-approved neoadjuvant therapies for ER- breast cancers, few good options exist for ER+ patients, which account for approximately 78% of breast cancers. Current treatment approaches for premenopausal women diagnosed with ER+ breast cancer include ovarian suppression, which can induce menopause and dramatically impact a patient's quality of life. Additionally, MBD affects more than 10 million women in the United States and many millions more worldwide. Increased MBD reduces the ability of mammograms to detect cancer. Studies have also shown that women with MBD have an increased risk of developing breast cancer and that the higher the MBD, the higher the incidence of breast cancer.

"There are a number of research-level medical applications of endoxifen outside of breast cancer, including in bipolar disorder disease in adults and in modulating genetically modified, cell-based therapies for cancer and immune diseases, that may require access to our endoxifen patents and technologies," continued Dr. Quay. "Atossa will monitor these activities carefully as they approach commercialization, with an eye to establishing appropriate licensing arrangements for the benefit of Atossa shareholders."

ABOUT (Z)-ENDOXIFEN
(Z)-endoxifen is the most active metabolite of the FDA approved Selective Estrogen Receptor Modulator (SERM), tamoxifen. Studies by others have demonstrated that the anti-estrogenic effects of tamoxifen are driven in a concentration-dependent manner by (Z)-endoxifen. In addition to its anti-estrogen effects, (Z)-endoxifen at higher concentrations has been shown to target PKCβ1, a known oncogenic protein.

Atossa has developed 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 converts a greater 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. We currently are

studying our (Z)-endoxifen in healthy women with measurable breast density and premenopausal women with ER+/HER2- breast cancer.

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 current focus on breast cancer and lung injury caused by cancer treatments. For more information, please visit www.atossatherapeutics.com

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FORWARD LOOKING STATEMENTS
Forward-looking statements in this press release, which Atossa undertakes no obligation to update, are subject to risks and uncertainties that may cause actual results to differ materially from the anticipated or estimated future results, including the risks and uncertainties associated with any variation between interim and final clinical results, actions and inactions by the FDA, the outcome or timing of regulatory approvals needed by Atossa including those needed to commence studies of AT-H201 and (Z)-endoxifen, lower than anticipated rate of patient enrollment, estimated market size of drugs under development, the safety and efficacy of Atossa's products, performance of clinical research organizations and investigators, obstacles resulting from proprietary rights held by others such as patent rights, whether reduction in breast density or in Ki-67 or any other result from a neoadjuvant study is an approvable endpoint for (Z)-endoxifen, whether Atossa can complete acquisitions, and other risks detailed from time to time in Atossa's filings with the Securities and Exchange Commission, including without limitation its periodic reports on Form 10-K and 10-Q, each as amended and supplemented from time to time.