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Atossa Genetics Completes Enrollment in Phase 2 Study of Topical Endoxifen in Women with Mammographic Breast Density

SEATTLE, Oct. 11, 2018 (GLOBE NEWSWIRE) -- Atossa Genetics Inc. (NASDAQ:**ATOS**), a clinical-stage biopharmaceutical company developing novel therapeutics and delivery methods for breast cancer and other breast conditions, has completed enrollment in its Phase 2 study of Atossa's proprietary Topical Endoxifen in women with mammographic breast density, or MBD.

This double-blinded, placebo-controlled Phase 2 study is being conducted at Stockholm South General Hospital in Sweden. The study is being led by principal investigator Dr. Per Hall, MD, Ph.D., Head of the Department of Medical Epidemiology and Biostatistics at Karolinska Institutet. "We are very pleased with the speed at which the study has fully enrolled 90 participants in under 6 weeks," commented Dr. Hall. "This fast enrollment is a testament to the hard work and superlative service of my dedicated staff and the positive experience patients have had with this novel topical drug," continued Dr. Hall.

Steve Quay, MD, Ph.D., CEO and President of Atossa, commented, "We are thrilled with Dr. Hall's and his team's work on our lead Endoxifen program and the rapid progress at his clinic. Quick enrollment in clinical trials can be a good indicator that there is strong demand for a therapy in an underserved market."

The primary endpoint of the study is to determine if daily Topical Endoxifen administration results in an individual change in MBD, which will be measured after three and six months of entering the study. The secondary endpoints are safety and tolerability. Ninety participants were randomized to one of three groups (one placebo group and two groups of different strengths of Topical Endoxifen) with 30 participants per group. The objective of the study is to determine if MBD is reduced, and if so, the results will drive sample size calculations for a future a Phase 3 study.

Summary of Atossa's Clinical Pipeline

Atossa has two development programs: Endoxifen (topical and oral forms) and a program for the targeted delivery of drugs and immunotherapies via its proprietary intra ductal microcatheters to treat early breast cancer.

Atossa's Endoxifen program consists of clinical studies to address the three segments of

the Breast Cancer Continuum as well as gynecomastia, and include:

- Phase 2 study to determine if Oral Endoxifen reduces tumor activity in early stage breast cancer patients in the “window of opportunity” between diagnosis of breast cancer and surgery (now open for enrollment in Australia)
- Phase 2 study to determine if Topical Endoxifen reduces MBD (enrollment completed in Sweden)
- A completed Phase 1 study of Topical Endoxifen in men that supports further development in men with gynecomastia induced by androgen deprivation therapy
- Phase 2 study of Topical Endoxifen to treat gynecomastia in men being treated with androgen deprivation therapy for prostate cancer (retaining CRO in Q4 2018)
- Phase 2 study of Oral Endoxifen for patients who are not benefiting from (meaning they are “refractory”) Tamoxifen (retaining CRO in Q4 2018)

Atossa’s Proprietary Topical Endoxifen

Atossa is developing its proprietary Topical Endoxifen to treat or prevent breast health conditions in both men and women. For women, the proprietary Topical Endoxifen is being developed to treat MBD. Legislation that has been recently enacted in over 30 states requires that women be notified if they have MBD and those notifications typically state that women with MBD have a higher risk of developing breast cancer, and that mammography may not be as effective in detecting breast cancer because the MBD can “mask” the detection of cancers.

As many as approximately 10 million women in the United States have high MBD, for which there is no FDA-approved treatment. MBD increases the risk of developing breast cancer. Although oral tamoxifen is approved to prevent new or recurrent estrogen-receptor positive early stage breast cancer and to treat metastatic breast cancer patients, it is rarely used in women who have not developed breast cancer who have an increased risk of developing breast cancer. Tamoxifen can have side effects that are difficult to tolerate and it has the risk of more serious side effects such as blood clots and strokes.

For men, Atossa is developing Topical Endoxifen to prevent a condition called gynecomastia, for which there is no FDA-approved pharmaceutical. Gynecomastia is male breast enlargement and accompanying pain, which according to the Mayo Clinic affects 25% of men in the U.S. between the ages of 50-69, or approximately 10 million men. It is the most common male breast disorder and is caused by a hormone imbalance where testosterone is low compared to estrogen. Gynecomastia is caused by, among other things, any number of commonly prescribed medications, such as androgen deprivation therapy to treat prostate enlargement and prostate cancer, anti-anxiety medications, cancer treatments (chemotherapy), and some heart medications. Subject to further clinical studies and regulatory approval, Topical Endoxifen could fill a significant unmet medical need in reducing gynecomastia in men taking androgen deprivation therapy to treat prostate cancer.

About Atossa Genetics

Atossa Genetics Inc., is a clinical-stage biopharmaceutical company developing novel therapeutics and delivery methods to treat breast cancer and other breast conditions. For more information, please visit **www.atossagenetics.com**.

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 preliminary 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, lower than anticipated rate of patient enrollment, estimated market size of drugs under development, the safety and efficacy of Atossa's products and services, performance of clinical research organizations and investigators, obstacles resulting from proprietary rights held by others with respect to fulvestrant, such as patent rights, potential market sizes for Atossa's drugs under development 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.

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