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Atossa Genetics Opens Its Phase 2 Study of Topical Endoxifen to Treat Mammographic Breast Density

SEATTLE, June 26, 2018 (GLOBE NEWSWIRE) -- Atossa Genetics Inc. (ATOS) ("Atossa" or the "Company"), a clinical-stage pharmaceutical company developing novel therapeutics and delivery methods to treat breast cancer and other breast conditions, today announced that it has opened its Phase 2 study of proprietary topical Endoxifen on mammographic breast density, or MBD, reduction. Studies by others have shown that a reduction in MBD reduces the risk of developing breast cancer and may potentially improve the accuracy of mammography in finding cancer.

The Phase 2 study is being conducted at Stockholm South General Hospital in Sweden and is being led by principal investigator Dr. Per Hall, MD, Ph.D., Head of the Department of Medical Epidemiology and Biostatistics at Karolinska Institutet.

"Opening our first Phase 2 study using our proprietary topical Endoxifen marks a major milestone in our clinical development," commented Steve Quay, Ph.D., MD, President and CEO of Atossa. "We look forward to working with Dr. Hall and his clinic to enroll women in this ground-breaking study and to move our topical Endoxifen a step closer to treating women with MBD. We are also making progress with our proprietary oral Endoxifen and have been evaluating a potential new indication in the pre-surgery, or "window of opportunity," setting which involves treating newly diagnosed breast cancer patients prior to surgery. We believe this indication could have a quicker clinical and regulatory pathway. We plan to start a Phase 2 study in the next quarter in this window of opportunity setting and/or a Phase 2 study in breast cancer survivors who are "refractory" to tamoxifen," added Dr. Quay.

The primary endpoint is to determine if 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 will be 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 Phase III study. Enrollment is anticipated to be completed by the end of 2018.

Atossa's Proprietary Endoxifen

Endoxifen is an active metabolite of tamoxifen. Tamoxifen is an FDA-approved drug to prevent new breast cancer as well as recurrent breast cancer in breast cancer patients.

Tamoxifen itself must be broken down by the liver into active compounds (metabolites), of which Endoxifen is the most active. Atossa has completed a comprehensive Phase 1 clinical study using both a topical and an oral formulation of Endoxifen. Results from the topical arm of the Phase 1 study indicated that the topical formulation was safe, well tolerated and that topical Endoxifen crossed the skin barrier in a dose-dependent fashion.

Topical Endoxifen Opportunities

Atossa is developing its proprietary topical Endoxifen to reduce MBD, which has been shown in studies conducted by others to be an independent risk factor for developing breast cancer. To date, 34 U.S. states have enacted laws requiring that findings of MBD be communicated to the patient. According to the National Cancer Institute approximately 10 million women in the U.S. have high breast density (BI-RAD level C or D with “D” being the highest). Although oral tamoxifen has been shown to reduce MBD, the benefit-risk ratio is generally not acceptable to most patients. For example, it is estimated that only ~ 2% of women at high-risk of developing breast cancer, including those with MBD, take oral tamoxifen to prevent breast cancer because of the risks of, or actual side-effects of, oral tamoxifen. There is no FDA-approved treatment for MBD.

Atossa is also developing topical Endoxifen for a condition in men called gynecomastia, which is male breast enlargement, and 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. In prostate cancer treatment, testosterone is suppressed with androgen deprivation therapy resulting is higher estrogen levels that usually triggers gynecomastia. One recent study indicates that up to 90% of men taking androgen deprivation therapy suffer from gynecomastia and breast pain (Handoo Rhee, et al., October 18, 2014, *BJU International*). There is no FDA-approved pharmaceutical to gynecomastia. Current therapeutic approaches in these patients include the daily use of oral estrogen-suppressing medications and prophylactic breast bud irradiation which is often repeated.

Atossa has completed dosing and clinical visits in a Phase 1 study in men using topical Endoxifen and it plans to announce preliminary results from this study in the third quarter 2018. The objectives of the placebo-controlled, repeat dose study of 24 healthy male volunteers are to assess the pharmacokinetics of a proprietary topical Endoxifen dosage form over 28 days, as well as to assess safety and tolerability.

About Atossa Genetics

Atossa Genetics Inc. is a clinical-stage pharmaceutical 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.

Atossa Genetics Company Contact:

Atossa Genetics Inc.
Kyle Guse
CFO and General Counsel
(O) 866 893-4927
kyle.guse@atossagenetics.com

Investor Relations Contact:

Scott Gordon
CoreIR
377 Oak Street
Concourse 2
Garden City, NY 11530
Office: 516 222-2560
scottg@CoreIR.com

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