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Atossa Genetics Opens Enrollment in Phase 2 Study of Oral Endoxifen to Treat Breast Cancer

SEATTLE, July 13, 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 a Phase 2 study of its proprietary oral Endoxifen to treat breast cancer in the "window of opportunity" setting, which is the period between diagnosis of breast cancer and surgery.

"Once a patient is diagnosed with breast cancer, there is a window of time, typically a number of weeks, before definitive surgery is performed," commented Steve Quay, Ph.D., MD, President and CEO of Atossa. "Our goal with this study is to show that our proprietary oral Endoxifen can modify the cancer activity in estrogen-receptor-positive patients during this 'window of opportunity.' Tamoxifen, the current standard of care, has not been effective in this setting, probably because it can take 50-200 days to reach steady-state of Endoxifen blood levels, while the surgery is usually completed within 30 to 45 days of diagnosis. Because our Phase 1 study indicated that our oral Endoxifen reaches therapeutic levels within 8 hours and therapeutic steady-state levels in only seven days, we are optimistic we can achieve a valuable treatment effect," added Dr. Quay.

The Pilot Phase of the study will initially enroll up to eight newly-diagnosed patients with Estrogen Receptor Positive (ER+) and HER2 negative (HER2-) stage 1 or 2 invasive breast cancer, requiring mastectomy or lumpectomy. Patients will receive Atossa's proprietary oral Endoxifen for at least 21 days from the time of diagnosis up to the day of surgery. Provided tumor activity reduction is demonstrated in at least two patients, an additional 17 patients will be enrolled for a total of 25. The U.S. FDA has provided a guidance document on "window of opportunity" or neoadjuvant studies entitled "Guidance for Industry Pathological Complete Response in Neoadjuvant Treatment of High-Risk Early-Stage Breast Cancer: Use as an Endpoint to Support Accelerated Approval." URL: https://www.fda.gov/downloads/drugs/guidances/ucm305501.pdf. The Company is using this document to inform this study and its design.

The primary endpoint is to determine if the administration of oral Endoxifen reduces the tumor activity as measured by Ki-67, which is a marker of cellular proliferation. The secondary endpoints are safety and tolerability and assessment of the study drug on expression levels of both estrogen and progesterone receptors. The impact on additional markers of cellular activity will also be explored.

The Phase 2 study is being conducted on behalf of Atossa by CPR Pharma Services Pty Ltd., Thebarton, SA, Australia. CPR Pharma recently completed the successful Phase 1 study of Atossa's oral and topical Endoxifen in women.

A summary of Atossa's current Endoxifen clinical pipe-line is as follows:

- Phase 2 study of oral Endoxifen to treat stage 1 or 2 breast cancer that is ER+ and HER2- in the "window of opportunity" setting: now open
- Phase 2 study of topical Endoxifen to treat mammographic breast density: opened in June 2018
- Phase 1 study of topical Endoxifen to treat gynecomastia in men: dosing and clinical visits completed; preliminary data to be reported in Q3 2018
- Phase 2 study of topical Endoxifen to treat gynecomastia in men: subject to Phase 1 results, the Phase 2 is anticipated to commence in Q4 2018
- Phase 2 study of oral Endoxifen to treat breast cancer survivors who are refractory to tamoxifen: anticipated to commence in 2H 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. Up to half of the patients taking tamoxifen, however, do not produce therapeutic levels of Endoxifen, frequently because of metabolism problems. Tamoxifen also has some very rare but serious adverse side effects, which can include stroke, blood clots, pulmonary embolism, blindness, and endometrial cancer. Because of these drawbacks of Tamoxifen, Atossa is developing oral and topical forms of Endoxifen.

Atossa has completed a comprehensive Phase 1 clinical study using both its topical and an oral formulation of Endoxifen. Results from the Phase 1 study indicated that there were no clinically significant safety signals and no clinically significant adverse events and both the oral and topical Endoxifen were well tolerated. In the topical arm of the study, low but measurable Endoxifen levels were detected in the blood in a dose-dependent fashion. In the oral arm of the study, participants exhibited dose-dependent Endoxifen levels that met or exceeded the published therapeutic level. The median time for patients in the study to reach the steady-state serum levels of Endoxifen while taking daily doses of Atossa's oral Endoxifen was 7 days. Published literature indicates that it takes approximately 50-200 days for patients to reach steady-state Endoxifen levels when taking daily doses of oral tamoxifen.

Oral Endoxifen Opportunities

In addition to the window of opportunity setting, Atossa is also developing our proprietary oral Endoxifen for breast cancer patients who are refractory to Tamoxifen. Approximately

one million breast cancer patients take Tamoxifen to prevent recurrent and new breast cancer; however, up to 50% of those patients are refractory to Tamoxifen, meaning they do not produce therapeutic levels of Endoxifen. This is often because the Tamoxifen is not properly metabolized into Endoxifen. “We believe our oral Endoxifen may provide an effective treatment supplement or option for these refractory patients because Endoxifen, unlike Tamoxifen, does not require liver metabolism,” stated Steve Quay.

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.

In June 2018, Atossa opened a Phase 2 double-blinded placebo-controlled study of topical Endoxifen to treat MBD. The study is being conducted at Stockholm South General Hospital in Sweden by principal investigator Dr. Per Hall, MD, Ph.D., Head of the Department of Medical Epidemiology and Biostatistics at Karolinska Institutet. The primary endpoint is MBD reduction, as well as safety and tolerability. The study includes 90 participants: 30 on each of two different doses of topical Endoxifen and 30 on placebo.

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 treat 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.

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