Atossa Genetics Launches Mens' Breast Health Program

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Commences Phase 1 Study of Topical Endoxifen in Men

SEATTLE, March 22, 2018 (GLOBE NEWSWIRE) -- Atossa Genetics Inc. (NASDAQ:ATOS), a clinical-stage pharmaceutical company developing novel therapeutics and delivery methods for breast cancer and other breast conditions, today announced that it has expanded its breast health program by launching a mens' breast health initiative with enrollment opening in a Phase 1 study of its proprietary topical Endoxifen in men. Tamoxifen is an active metabolite of tamoxifen, an FDA approved drug for breast cancer in women. The objectives of the placebo-controlled, repeat dose study of 24 healthy male volunteers are to assess the pharmacokinetics of proprietary topical Endoxifen dosage forms over 28 days, as well as to assess safety and tolerability.

Dr. Steven Quay, Ph.D., MD, President and CEO of Atossa, commented that "Initiating a program for mens' breast health is a natural extension for our proprietary Endoxifen, which has focused on women to date. This Phase 1 study of topical Endoxifen in men should serve as a foundation for future development into mens' breast health, including male breast cancer and gynecomastia. Men being treated for prostate cancer currently have limited options to address the gynecomastia that is associated with their cancer treatment, such as breast-bud irradiation, estrogen suppression therapy and surgery."

"After reviewing the data obtained from our recently-completed Phase 1 study in women, expanding our program to include the men, whose breast health is often underserved, was a logical next step. We have progressed rapidly in this endeavor having engaged the necessary contract research organizations and having submitted and received approval to open the study for enrollment. This will be the first of other studies targeting mens' breast health. We look forward to reporting progress on this study as well as the other anticipated studies we are commencing in 2018," concluded Dr. Quay.

The 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.

About Gynecomastia

Gynecomastia is male breast enlargement and accompanying pain. 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 resulting is higher estrogen levels that usually triggers gynecomastia. Prophylactic breast bud irradiation is commonly used in prostate cancer patients, but must often be repeated. 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*).

According to the Mayo Clinic, although it can affect men at almost any age, it is most prevalent in men ages 50-69, affecting at least 1 in 4 men in this age group. 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. Gynecomastia is not only painful and embarrassing, it can also cause men to stop taking these important medications.

There are no FDA-approved therapeutics for gynecomastia. Breast-bud irradiation, use of compression garments and plastic surgery are the most common approaches used to treat gynecomastia.

About Breast Cancer

The American Cancer Society (ACS) estimates that approximately 266,000 women will be diagnosed with breast cancer in the United States this year and that approximately 41,000 will die from the disease. It is the second leading cause of cancer death in American women. Although about 100 times less common than women, breast cancer also affects men. The ACS estimates that the lifetime risk of men getting breast cancer is about 1 in 1,000; 2,550 new cases of invasive breast cancer will be diagnosed; and 480 men will die from breast cancer in 2018.

Similar to women, the treatment for male breast cancer is typically surgery (with or without radiation) and chemotherapy. Breast cancer in men is deadlier than breast cancer in women: men with early-stage breast cancer have a lower five-year survival rate than women and breast cancer in men tends to be detected at a later stage of development than women (Jon M. Greif, DO, FACS, et al., May 2012, *American Society of Breast Surgeons*). Although tamoxifen is the standard of care for women to prevent new and recurrent breast cancer, there is no FDA-approved treatment for male breast cancer.

About Endoxifen

Oral tamoxifen has been widely used for over 40 years to both treat and prevent breast cancer. Tamoxifen, however, has significant drawbacks: First, it can cause side effects including headaches, nausea and early menopausal symptoms as well as rare but serious side effects such as cataracts, stokes and cancer of the uterus. Second, tamoxifen is a "pro-drug," meaning that it must be processed by the liver in order to produce therapeutic ("active") metabolites. The metabolite in tamoxifen that accounts for most of its therapeutic activity is called Endoxifen. Unfortunately, up to 50% of breast cancer survivors who are taking tamoxifen do not produce therapeutic levels of Endoxifen (meaning they are "refractory") for a number of reasons, including that they, due to their genotype, do not have the requisite liver enzymes. Additionally, it can take from 50-200 days for tamoxifen to reach "steady-state" meaning that the drug may be providing little or no benefit for up to several months after starting treatment.

Atossa is developing topical Endoxifen for women with mammographic breast density, or MBD, and for men with gynecomastia or breast cancer.

There is no FDA-approved therapeutic for gynecomastia and male breast cancer. We estimate that approximately ten million women in the Unites States have MBD, for which there is no FDA-approved treatment. Although oral tamoxifen is approved to prevent breast cancer in “high-risk” women, it is used by less than 5% of women with an increased risk of developing breast cancer because of the actual or perceived side effects and risks of tamoxifen. We believe our topical Endoxifen may provide an effective treatment for MBD because, unlike an oral medication, it is applied directly to the breast and penetrates the skin; it does not require metabolism by the liver; and it may produce fewer side effects than tamoxifen. Moreover, our topical Endoxifen may improve mammography accuracy and patient care by unmasking cancerous tumors that are otherwise hidden by breast density, and reduce the risks of over diagnosing potential tumors when more highly sensitive imaging methods are used.

Second, we are developing 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. 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.

We recently completed a comprehensive Phase 1 study in 48 healthy women in Australia using both the topical and oral forms of our proprietary Endoxifen. We concluded that all objectives were successfully met in both arms of the study: 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, there were low but measurable Endoxifen levels detected in the blood in a dose-dependent fashion and in the oral arm of the study participants exhibited dose-dependent Endoxifen levels in published reports of the therapeutic range. The median time for patients in the study to reach the steady-state serum levels of Endoxifen while taking daily doses of 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. Finally, the median time for patients in the study to reach the maximum serum level of Endoxifen after taking Atossa’s oral Endoxifen ranged from 4 to 8 hours (depending on dose). The 4 mg dose of Endoxifen produced a maximum serum level of Endoxifen in 4 to 8 hours at levels above the generally accepted threshold for a therapeutic effect on estrogen-dependent breast cancer.

In September 2017, we contracted Stockholm South General Hospital in Sweden to conduct a Phase 2 study of our topical Endoxifen. The primary endpoint is MBD reduction, as well as safety and tolerability. We are planning to open this study in the first half of 2018 and to complete it in the second half of 2018. We plan to commence a Phase 2 clinical study using our oral Endoxifen for patients who are refractory to tamoxifen. We have retained a clinical research organization to manage the study and we plan to open the study in the first half of 2018 and to complete it in the second half of 2018. We have now opened enrollment in our Phase 1 study of topical Endoxifen in men.

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, lower than anticipated rate of patient enrollment, preliminary and final results of clinical studies, 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, 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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