September 13, 2018

Atossa Genetics Announces Preliminary Results from Male Phase 1 Study of Topical Endoxifen

*****All Objectives Successfully Met*****

Conference Call to Be Held Today at 10 am Eastern Time

SEATTLE, Sept. 13, 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, reported preliminary results from its Phase 1 dose- escalation study of its proprietary topical Endoxifen in male subjects. All objectives were successfully met:

- **Safety:** There were no clinically significant safety signals and no clinically significant adverse events in participants receiving topical Endoxifen.

- **Tolerability:** Topical Endoxifen was well tolerated at each dose level and for the dosing duration utilized in the study.

- **Pharmacokinetics:** Blood samples showed no measurable topical Endoxifen.

“Based on these positive preliminary results, we are advancing our topical Endoxifen into a Phase 2 study to reduce gynecomastia in men starting prostate cancer therapy,” commented Dr. Steven C. Quay, CEO and President. “We anticipate retaining a clinical research organization to manage that study in the fourth quarter 2018. In addition to advancing our mens’ program into a Phase 2 study, we also have multiple Phase 2 studies in women addressing large markets with significant unmet needs: breast cancer and a condition called mammographic breast density. We look forward to reporting progress on these programs in the fourth quarter 2018 and into 2019,” added Dr. Quay.

Summary of Atossa’s Clinical Pipeline

Atossa’s current programs include:

Topical Endoxifen

- Phase 2 study to determine if topical Endoxifen reduces mammographic breast density (now enrolling in Sweden)
- Phase 1 study of topical Endoxifen in men (study complete with preliminary results

announced today)
- Phase 2 study of topical Endoxifen to treat gynecomastia in men being treated for prostate cancer (retaining CRO in Q4 2018)

Oral Endoxifen

- 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 enrolling in Australia)
- Phase 2 study of oral Endoxifen for patients who are “refractory” to Tamoxifen (retaining CRO in Q4 2018)

Intraductal Delivery

- Phase 2 study of Atossa’s proprietary intraductal microcatheter technology to administer Fulvestrant in cancer patients prior to surgery (now enrolling in the U.S. at Montefiore Medical Center, NY)
- Immuno-oncology (e.g., CAR-T) research

The Phase 1 Study Topical Endoxifen Study in Men
The Phase 1 study was a double-blind, randomized, placebo-controlled, repeat dose study of 24 healthy male subjects. Safety, tolerability and the pharmacokinetics of proprietary topical Endoxifen formulation at varying dose levels over 28 days were assessed. The study was conducted on behalf of Atossa by CPR Pharma Services Pty Ltd., Thebarton, SA, Australia.

Atossa’s Proprietary Topiocal Endoxifen
We are developing our proprietary topical Endoxifen to treat or prevent several health conditions in both men and women. For men, we are developing topical Endoxifen to prevent a condition called gynecomastia. 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 levels are lower than 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.

Gynecomastia is not only painful and embarrassing, it can also cause men to stop taking their prescribed medication. In prostate cancer treatment, testosterone is suppressed resulting in higher estrogen levels that often 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 use of daily oral estrogen-suppressing medications and prophylactic breast bud irradiation which is often repeated. Gynecomastia can create quality of life issues, with some patients attempting to hide the condition with compression garments and, in some cases, undergoing plastic surgery. We

believe, subject to further clinical studies and regulatory approval, that our topical Endoxifen could fill a significant unmet medical need in reducing the risk of gynecomastia in men taking certain therapies to treat prostate cancer and helping them maintain their quality of life.

For women, we are also developing topical Endoxifen to treat mammographic breast density or MBD. Legislation has been recently enacted in over 30 states requiring women be notified if they have MBD. These 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. We estimate that approximately 10 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 are conducting a double-blinded, placebo-controlled Phase 2 study at Stockholm South General Hospital in Sweden using our topical Endoxifen. 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 in Stockholm. The primary endpoint 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 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. We expect to complete enrollment by the end of 2018.

Conference Call

Atossa Genetics will host a conference call to discuss preliminary results today at 10 am Eastern time.

Due to expected high call attendance, participants are asked to preregister for the call through the following link: http://dpregister.com/10124008. Please note that registered participants will receive their dial in number upon registration and will dial directly into the call without delay. Those without internet access or who are unable to pre-register may dial in by calling: 1-844-824-3830 (domestic), 1-412-317-5140 (international) and Canada Toll Free: 1-855-669-9657. Callers should ask to be joined into the Atossa Genetics call.

The conference call will also be available through a live webcast at https://services.choruscall.com/links/atos180913.html which is also available at www.atossagenetics.com on the Company's IR events page at http://ir.atossagenetics.com/ir-calendar.

Management will answer pre-submitted questions gathered prior to the conference call in the Question and Answer period of the call. Interested parties may submit questions for management's consideration prior to the call by submitting them in writing to Atossa Genetics' Investor Relations at scottg@coreir.com.

A replay of the call will be available approximately one hour after the end of the call through October 13, 2018. The replay can be accessed via Atossa's website or by dialing 877-344-7529 (domestic) or 412-317-0088 (international) or Canada Toll Free at 855-669-9658. The replay access code is 10124008.

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.

Atossa Genetics Company Contact:

Atossa Genetics Inc.
Kyle Guse
CFO and General Counsel
Office: 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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