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

***All Objectives Successfully Met***

Conference Call To Be Held Today at 2pm Eastern Time

SEATTLE, Sept. 14, 2017 (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, reported preliminary results from its Phase 1 dose escalation study of its proprietary topical Endoxifen. 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:** Topical Endoxifen crossed the skin barrier when applied daily to the breast, as demonstrated by low but measurable Endoxifen blood levels detected in a dose-dependent fashion.

These data demonstrate the suitability of topical endoxifen for further clinical development.

Atossa expects to announce results from the oral arm of the Phase 1 study in the next 30-60 days.

**The Phase 1 Study**

The Phase 1 study was a double-blind, placebo-controlled, repeat dose study of 48 healthy female subjects. Atossa assessed safety, tolerability and the pharmacokinetics of proprietary formulations of both topical and oral Endoxifen dosage forms in varying dose levels over 28 days. The study was conducted in two parts based on route of administration. Results from the oral arm of the study are expected in the next 30 to 60 days.

**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.

**Topical Endoxifen.** A condition called breast density (or, MBD), typically diagnosed by a mammogram, has been shown to be an independent breast cancer risk factor. To date, 30 states require that findings of MBD be directly communicated to the patient. We believe a topical form of Endoxifen could potentially reduce MBD. Although oral tamoxifen has been shown to reduce MBD, the benefit-cost ratio is not acceptable to most physicians and their 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 risk of, or actual side-effects of, oral tamoxifen. Therefore we expect our next study to focus on the potential for Atossa’s topical Endoxifen to reduce MBD.

**Oral Endoxifen.** Although approximately one million breast cancer survivors take tamoxifen annually, up to half of them do not benefit from tamoxifen, meaning they are “refractory,” for a number of reasons including that they do not properly metabolize tamoxifen. Low endoxifen levels in breast cancer patients taking oral tamoxifen are associated with an increased risk of recurrence or the development of new breast tumors. Thus providing oral Endoxifen directly to the patient without having to be metabolized may help to address this problem.

Based on the number of women at high-risk of developing breast cancer and the number of patients who have survived breast cancer but are not benefiting from tamoxifen, Atossa estimates that the potential markets for its proprietary oral and topical formulations of Endoxifen could each potentially exceed $1 billion in annual sales.

**Next Steps**

“Based on these positive preliminary results, we are advancing our topical Endoxifen into Phase 2 studies,” commented Dr. Steven C. Quay, CEO and President. “We look forward to announcing the results from the oral arm of our Phase 1 study in the coming 30 to 60 days,” continued Dr. Quay.

**Breast Cancer Statistics**

The American Cancer Society (ACS) estimates that approximately 250,000 women will be diagnosed with breast cancer in the United States this year and that approximately 40,000 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; 2,470 new cases of invasive breast cancer will be diagnosed; and 460 men will die from breast cancer in 2017.

**Conference Call**

Atossa Genetics will host a conference call to discuss preliminary results today at 2pm
eastern time.

To listen to the call by phone, interested parties within the U.S. should call 1-844-824-3830 and International callers should call 1-412-317-5140. All callers should ask for the Atossa Genetics conference call. The conference call will also be available through a live webcast at www.atossagenetics.com. Details for the webcast may be found on the Company’s IR events page at http://ir.atossagenetics.com/ir-calendar.

A replay of the call will be available approximately one hour after the end of the call through October 14, 2017. 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 conference ID number is 10112105.

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, 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