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

All Objectives Successfully Met

Conference Call To Be Held Today at 10 am Eastern Time

SEATTLE, Oct. 25, 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 study of its proprietary oral Endoxifen. All objectives were successfully met:

– Safety: There were no clinically significant safety signals and no clinically significant adverse events in participants receiving oral Endoxifen.

– Tolerability: Oral Endoxifen was well tolerated at each dose level and for the dosing duration utilized in the study.

– Pharmacokinetics: Oral Endoxifen demonstrated blood levels that have been associated with a therapeutic effect in the adjuvant setting in women with breast cancer.

These data demonstrate the suitability of oral Endoxifen for further clinical development.

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. Preliminary results from the topical arm of the study were announced on September 14, 2017.

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 is a "pro-drug" meaning that it must be broken down by the liver into active

compounds (metabolites), of which Endoxifen is the most active. It is these active metabolites that have the therapeutic effect.

Oral Endoxifen. Although approximately one million breast cancer survivors take tamoxifen annually, up to half of them do not fully benefit from tamoxifen, meaning they are “refractory,” for a number of reasons including that they do not properly metabolize tamoxifen into its active metabolites. 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.

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 less than 5% of women at an increased 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. We are planning a Phase 2 study of topical Endoxifen in Stockholm, Sweden for the treatment of MBD.

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

Next Steps

“Based on these positive preliminary results, we are advancing our oral Endoxifen into Phase 2 studies,” commented Dr. Steven C. Quay, CEO and President. “We expect our initial Phase 2 study will be in women who are refractory to tamoxifen and we expect to begin that study in the first quarter of 2018,” 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 10 am Eastern time.

To listen to the call by phone, interested parties within the U.S. should call 1-844-824-

3830, International callers should call 1-412-317-5140 and Canadian callers should call 1-855-669-9657. 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 November 24, 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 10113835.

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.

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