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Atossa Genetics Announces the Opening of Its First Phase 2 Clinical Trial of Intraductal Fulvestrant Administration in Women With Ductal Carcinoma in Situ (DCIS) or Breast Cancer

SEATTLE, WA -- (Marketwired) -- 03/02/16 -- Atossa Genetics Inc. (NASDAQ: ATOS), a healthcare company developing novel pharmaceutical delivery methods to address breast conditions, including cancer, announced today that the "007" trial, a Phase 2 study in women with ductal carcinoma *in situ* (DCIS) or invasive breast cancer slated for mastectomy, is open for enrollment. This study will assess the safety and tolerability of fulvestrant when delivered directly into breast milk ducts of these patients. Approval from the institutional review board was received yesterday.

Although breast cancers and precancerous lesions are detected at an earlier stage, and despite the use of systemically administered agents such as tamoxifen and fulvestrant (Faslodex®), serious side effects remain a major challenge, and may lead to poor patient compliance with these drug regimens. The American Cancer Society estimates that over 292,000 American women were diagnosed with breast cancer (both local and invasive) in 2015. They also estimate that over 40,000 women died in 2015 due to their disease. Providing drug directly into the ducts targeting the site of the localized cancerous lesions could reduce the need for systemic anti-cancer drugs, and potentially reduce or eliminate the systemic side effects of the drugs and morbidity in such patients and ultimately improve patient compliance.

About the "007" Trial

This Phase 2 clinical trial is an open-label comparative study of the distribution of fulvestrant in women scheduled for mastectomy. The first six study participants will receive the standard intramuscular fulvestrant dose of 500 mg to establish the reference drug distribution. The subsequent 24 participants will receive fulvestrant by intraductal instillation utilizing Atossa's patented investigational microcatheter device. The total dose administered in this manner will not exceed 500 mg.

The primary endpoint of the clinical trial is to assess the safety and tolerability of intraductal administration of fulvestrant in women with DCIS or Stage 1 or 2 invasive ductal carcinoma prior to mastectomy. The secondary objective of the study is to determine if there are changes in the expression of Ki67 as well as estrogen and

progesterone receptors between a pre-fulvestrant biopsy and post-fulvestrant surgical specimen. Mammography before and after drug administration in both groups will be performed to determine the effect of fulvestrant on breast density of the participant.

Atossa owns one issued patent and several pending applications directed to the treatment of breast conditions, including cancer, by the intraductal administration of fulvestrant and other pharmaceuticals.

Additional information about the study can be found at: https://clinicaltrials.gov/ct2/show/NCT02540330?term=atossa&rank=2.

Dr. Steven Quay, Chairman, CEO & President of Atossa Genetics commented, "We are pleased to open the "007" trial for patient enrollment, which will further our understanding of the potential of intraductal delivery of therapeutics for the treatment of various breast disorders. DCIS is a serious medical condition diagnosed in approximately 60,000 women a year in the U.S. The current treatment options for these women, which include, chemotherapy, surgery and/or radiation, are expensive, invasive and in some cases may not be entirely necessary."

About Atossa Genetics
Atossa Genetics Inc., is developing novel and locally-administered pharmaceuticals to address breast conditions, including cancer. 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 actions and inactions by the FDA, the outcome or timing of regulatory approvals needed by Atossa, lower than anticipated rate of patient enrollment, 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.

For Additional Information

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