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Atossa Genetics Receives Positive Interim Review from Independent Safety Committee in Phase 1 Topical Endoxifen Dose Escalation Study in Men

SEATTLE, April 24, 2018 (GLOBE NEWSWIRE) -- Atossa Genetics Inc. (ATOS) (“Atossa” or the “Company”), a clinical-stage pharmaceutical company developing novel therapeutics and delivery methods to treat breast cancer and other breast conditions, today announced that it has received a positive interim review on its Phase 1 study of topical endoxifen in men, which is being developed to address gynecomastia (or male breast enlargement), which is a common condition in patients being treated for prostate cancer. The Independent Safety Committee reviewed the blinded data generated from the first group in the study (eight subjects) and concluded that the study may advance to the next dosing level.

"This positive safety determination is on the critical path for a successful outcome of this Phase 1 study in men," stated Dr. Steven Quay, Ph.D., MD, President and CEO of Atossa. "It is the first assessment of our clinical safety and tolerability data and it indicates that proceeding to the next dosing level with our proprietary topical endoxifen is warranted. We can now advance to the next level of the study which is to escalate the dosage in a new cohort of subjects as we continue to monitor safety and tolerability in the first cohort of the study.” Dr. Quay added, “We believe this is the first clinical trial ever conducted of a topical pharmaceutical for the treatment of gynecomastia. There are no approved drugs, either topical or oral, for this important, unmet medical need which affects 25% of men ages 50-69.”

The objectives of this double-blinded, placebo-controlled, repeat dose study of 24 healthy male subjects is to assess the pharmacokinetics of proprietary formulations of topical endoxifen dosage forms over 28 days, as well as to assess safety and tolerability. The study is being conducted on behalf of Atossa by CPR Pharma Services Pty Ltd., Thebarton, SA, Australia.

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 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 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.

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