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Atossa Genetics Acquires Rights to Clinical Stage Proprietary Afimoxifene Gel for Potential Treatment of Hyperplasia of the Breast

Sixteen Completed Clinical Studies Provide Support for Phase 2 Program

SEATTLE, WA -- (Marketwired) -- 05/18/15 -- Atossa Genetics, Inc. (NASDAQ: ATOS) today announced that it has acquired from Besins Healthcare an exclusive license to Besins' patented gel formulation of 4-Hydroxytamoxifen, or Afimoxifene Gel, which Atossa intends to develop for the potential treatment of hyperplasia of the breast.

Steven C. Quay, M.D., Ph.D., President and CEO, commented, "Atossa's strategy is to improve breast health through a three step approach: providing our patented medical devices to collect nipple aspirate fluid, testing the fluid for the presence of hyperplasia, and then treating the hyperplasia with the local delivery of a proprietary pharmaceutical. Obtaining the rights to Besins' Afimoxifene Gel represents considerable advancement towards developing the crucial third step of this process."

"Besins has developed substantial pre-clinical and clinical data that we intend to utilize to advance the Afimoxifene Gel, to be used in conjunction with our devices and laboratory tests. We intend to secure a manufacturing source for a clinical supply of Afimoxifene Gel and to advance the clinical development into a Phase II clinical trial using our proprietary devices, laboratory tests and the Afimoxifene Gel. Besins is a recognized leader in the development and commercialization of hormone therapies and we believe their proprietary Afimoxifene Gel may, in conjunction with our breast aspirator devices and cytology tests, be developed as a local treatment for hyperplasia," commented Dr. Quay.

Leslie Grunfeld, CEO of Besins Healthcare, commented, "Besins Healthcare has spent a number of years developing and advancing Afimoxifene Gel. We are pleased that Atossa, who are focused on breast health, will continue the development for the treatment of local hyperplasia in conjunction with their existing technology. Various studies have shown that Afimoxifene Gel could be effective for other related indications and we are hopeful to be able to develop these in the future."

Key terms of the license are:

- Exclusive world-wide rights to develop and commercialize Afimoxifene Gel for the potential treatment and prevention of hyperplasia of the breast.
- No upfront or milestone payments to Besins.
- Royalty of 8% - 9% of net sales for the first 15 years of commercialization.
- Atossa has the non-exclusive right to also develop Afimoxifene Gel for breast cancer and other breast diseases (subject to milestone payments for these additional indications).
- Atossa obtains access to Besins' pre-clinical and clinical studies and data for the treatment of breast pain with Afimoxifene Gel, which include animal, toxicity, and clinical trials with 144 patients. Results from additional 82 patients have been published from pre-surgical studies in invasive breast cancer and ductal carcinoma in situ, or DCIS, conducted respectively in France and the United States. Across all indications, over 450 patients have been treated with Afimoxifene Gel.
- Besins has the right of first refusal to commercialize the Afimoxifene Gel on a country-by-country basis in countries where they have a marketing presence.

"One of our four key objectives for 2015 is to commence a clinical study using a local therapy to treat a serious breast health condition. This new exclusive license arrangement with Besins significantly advances this key objective," continued Dr. Quay.

About Atossa Genetics

Atossa Genetics Inc. is focused on improving breast health through the development of laboratory services, medical devices and therapeutics. The laboratory services are being developed by its subsidiary, The National Reference Laboratory for Breast Health, Inc. The laboratory services and the Company's medical devices are being developed so they can be used as companions to therapeutics to treat various breast health conditions. For more information, please visit www.atossagenetics.com.

About Besins Healthcare

Besins Healthcare is a privately owned pharmaceutical company specialized in the development and worldwide diffusion of innovative drugs for the well-being of men and women throughout their lives. Over the last 30 years Besins Healthcare has established a strong and reputable name in the production of innovative drugs for the treatment of gynecological, fertility and obstetrical conditions as well as androgen deficiency.

Besins has become a renowned player in the area of hormonal therapies. Innovative products from Besins Healthcare are distributed in more than 90 countries around the world through subsidiary companies as well as a network of business partners.

About Afimoxifene and Afimoxifene Gel

Afimoxifene (4-hydroxytamoxifen), an active metabolite of tamoxifen, is an anti-estrogen with an affinity for estrogen receptor that is up to 50 fold higher compared with that of

tamoxifen. Afimoxifene Gel is a proprietary transdermal gel formulation of Afimoxifene protected by 10 patent families. It can be dispensed from a convenient metered-dose container. Besins has completed a comprehensive preclinical pharmacology and toxicology package on Afimoxifene Gel and its manufacturing CMC package is expected to be sufficient to support Atossa's Phase 3 Program. A total of 16 Phase-1 and -2 studies have been conducted in a variety of indications in the United States, United Kingdom, France, Poland, and Czech Republic. These studies enrolled over 450 patients total, and results were published in leading medical journals such as the *Journal of Clinical Oncology (J Clin Oncol 2005;23:2980-87)*, *Clinical Cancer Research (Clin Cancer Res 2014;20:3672-82)*, and *Breast Cancer Research and Treatment (Breast Cancer Res Treat 2007;106:389-97)*. Systemic distribution of topically delivered Afimoxifene Gel was minimal with little difference in adverse events between Afimoxifene Gel and placebo. The occurrence of hot flushes or night sweats, vaginal dryness, vaginal bleeding, and nipple discharge were similar between the treatment arm and placebo.

Forward-Looking Statements

Forward-looking statements in this press release 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 by the FDA, the outcome or timing of regulatory approvals needed by Atossa to sell its products, responses to regulatory matters, Atossa's ability to achieve its objectives, continue to manufacture and sell its products, recalls of products, the safety and efficacy of Atossa's products and services, performance of distributors, whether Atossa can launch and commercialize in the United States and foreign markets the additional tests, devices and therapeutics in its pipeline in a timely and cost effective manner, 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's products, services and pharmaceuticals described herein will require FDA approval before they can be marketed. Atossa does not undertake any obligation to update any forward looking statement.

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