August 20, 2014

Atossa Genetics Announces Submission of Additional Information to the FDA in Support of 510(k) for the ForeCYTE Breast Aspirator

SEATTLE, WA -- (Marketwired) -- 08/20/14 -- Atossa Genetics Inc. (NASDAQ: ATOS) today announced that it has submitted additional information to the U.S. Food and Drug Administration in response to the FDA's February 21, 2014 request. The information was provided in support of Atossa's 510(k) submission for the ForeCYTE Breast Aspirator. The response includes, among other things:

- Data from an IRB-approved, prospective, single-arm, multi-laboratory, non-randomized, non-masked clinical trial in adult women using the ForeCYTE Breast Aspirator for the collection, fixation, transport, and processing of NAF specimens for laboratory cytological testing at multiple, independent CLIA-registered laboratories.
- A study of the concordance of positive and negative control Reference Panel Specimens with a blinded cytological interpretation when the specimens were processed and read at multiple, independent laboratories.
- Study data to establish shelf life information and document shipping stability under adverse conditions of the ForeCYTE Breast Aspirator.

Based on the information provided to the FDA, Atossa expects that the FDA will finalize their review process, which may include requests for additional information, and will either clear Atossa's 510(k) submission or provide a "not substantially equivalent" decision on Atossa's 510(k) submission.

About Atossa Genetics

Atossa Genetics Inc. is focused on improving breast health through the development of laboratory developed tests (LDTs), medical devices and therapeutics. The Company's LDTs are being developed by its subsidiary, The National Reference Laboratory for Breast Health, Inc. The LDT's 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 additional information, please visit www.atossagenetics.com.

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, including timing of review by the FDA of 510(k) submissions, and actions related thereto including whether the FDA agrees with study design, protocol and conclusions, whether Atossa can submit additional information to the FDA in a timely fashion and whether the FDA will find that information acceptable and/or request additional information and/or clear the ForeCYTE Breast Aspirator for marketing in the U.S., the outcome of the FDA re-inspection completed on March 14, 2014, the outcome or timing of regulatory clearances needed by Atossa to sell its products, responses to regulatory matters, Atossa's ability to continue to manufacture and sell its products, recalls of products, the efficacy of Atossa's products and services, performance of distributors, estimated future expenses and cash needs, whether Atossa can launch 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.

Source: Atossa Genetics Inc