October 4, 2013

Medical Device Voluntary Recall - News Release

ForeCYTE Breast Health Test; Mammary Aspiration Specimen Cytology Test (MASCT)

SEATTLE, WA -- (Marketwired) -- 10/04/13 -- Atossa Genetics Inc. (NASDAQ: ATOS)

1616 EastLake Ave East, Suite 510
Seattle, WA 98102
(800) 351-3902
www.atossagenetics.com
www.GetForecyte.com
www.nrlbh.com

On October 4, 2013 Atossa Genetics Inc. (NASDAQ: ATOS) initiated a voluntary recall to remove the ForeCYTE Breast Health Test and the Mammary Aspiration Specimen Cytology Test (MASCT) device from the market. This voluntary recall includes the MASCT System Kit and Patient Sample Kit. The vast majority of these products (approximately ninety percent) are in inventory with Atossa's distributors and the remaining quantities are at customer sites across the United States. Distributors and customers should stop using affected products and return them to Atossa immediately.

Atossa is removing the ForeCYTE Breast Health Test and the MASCT device from the market to address concerns raised by the U.S. Food and Drug Administration (FDA) in a warning letter received by Atossa in February 2013. The FDA raised concerns about (1) the current instructions for use (IFU); (2) certain promotional claims used to market these devices; and (3) the need for FDA clearance for certain changes made to the Nipple Aspirate Fluid (NAF) specimen collection process identified in the current IFU. Atossa will remove existing product from the market until FDA's concerns are addressed.

The MASCT device has been cleared by the FDA for use as a sample collection device, with the provision that the fluid collected using this device can be used to determine and/or differentiate between normal, pre-cancerous, and cancerous cells. The MASCT device has not been cleared by the FDA for the screening or diagnosis of breast cancer. In addition, the ForeCYTE Breast Health Test has not been cleared or approved by the FDA for any indication. The ForeCYTE Breast Health Test and the MASCT device are not a

replacement for screening mammograms, diagnostic imaging tests, or biopsies. Patients should follow the recommendations and instructions of their physician with respect to breast cancer screening and diagnosis.

To date, Atossa is unaware of any adverse incidents or injuries associated with the use of the ForeCYTE Breast Health test and the MASCT device or the processing method currently identified in the IFU. Additionally, Atossa is unaware of any risk to health or injury for clinicians or the patient population that have used these devices. However, these devices may produce false positive or false negative results. Although not cleared or intended for this use, if these devices are used as a substitute for recommended screening or diagnosis of breast cancer, FDA is concerned that patients may choose to forgo recommended mammograms and necessary biopsies.

Atossa is working with the FDA on this matter and this voluntary recall. Atossa is notifying its distributors and customers by certified mail and is arranging for the return of all recalled product(s). Products affected by this recall are listed in the table below (table 1):

TABLE 1

Product Code	***Part Number***	***Description***	***Lot Number***
AG-MASCT	9002528	MASCT System Kits	All
AG-MASCT	9002528MD	MASCT System Kits	All
DTG-MASCT	9002587	Clarity System Kits	All
AG-FC5	9002513	MASCT Patient Sample Kits	All
AG-FC5	9002513MD	MASCT Patient Sample Kits	All
DTG-FC5	9002614	Clarity Patient Sample Kits	All
NRLBH-5	9002717MD	Nipple Aspirate Fluid Laboratory Kit	All

MASCT System Kit	***Patient Sample Kit***
1. MASCT Breast Pump 2. Instructions for Use (IFU) 3. Heating Pad 4. Timer 5. Saccomono's Fixative 6. Nu Prep Gel 7. Welcome and Training Materials Coversheet 8. MASCT System Order Form 9. ForeCYTE Training Video DVD	1.) Two (2) flower assemblies (e.g., filter, filter retainer, and filter holder), 2.) Instructions for Use (IFU) 3.) Two (2) specimen collection devices, 4.) Two (2) breast bags for transporting the specimen collection container 5.) Barcode labels 6.) Saccomono's Fixative 7.) Nu Prep Gel 8.) MASCT System package insert

10. MASCT System Instructions with pictures - pink	9.) ForeCYTE Test Requisition Form 10.) Patient Information Sheet 11.) Atossa Patient Information 12.) FED EX Clinical PAK 13.) MASCT System Order Form 14.) FED EX Pouch 15.) FED EX Airbill

Distributors and customers should contact Atossa at 800-351-3902 to obtain instructions on how to return these products. Customers with questions may contact the company via telephone at 1-888-219-4629 at any time.

Any problems experienced with the use of this product may be reported to the FDA: at http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm

- Online (form available to fax or mail), or call FDA 1-800-FDA-1088

Contact:

Atossa Genetics Inc.:

Steven C. Quay
President and Chief Executive Officer
800-351-3902
Email Contact

Kyle Guse
Chief Financial Officer and General Counsel
800-351-3902
Email Contact

Investor Relations:

Matthew D. Haines
Managing Director
MBS Value Partners
212-710-9686
Email Contact

Source: Atossa Genetics, Inc.