

# Provista

DIAGNOSTICS®

Precision Diagnostics to Enhance  
Women's Health



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## **Provista Diagnostics, Inc. Completes Enrollment of the 2<sup>nd</sup> Cohort of its 002 Prospective, Multi-Center, Randomized Trial Utilizing the Provista Biomarker Assay to Aid in the Detection of Breast Cancer**

**New York, NY** – August 13, 2015 – Provista Diagnostics, Inc., a privately-held molecular diagnostics company developing and commercializing a new generation of proprietary blood-based diagnostic, prognostic, and monitoring tests designed to address the unmet needs in woman’s cancer including breast and gynecologic cancers, today announced that they completed enrollment of the 2nd cohort of a prospective study of their protein-based biomarker blood test to aid in detection of breast cancer.

Provista’s 2nd cohort of its 002 study enrolled a total of 509 women that will be monitored for 6 and 12 months for clinical outcomes. Together, cohorts 1 and 2 of Provista’s 002 study has recruited a total of 1,020 patients. The study is a prospective, multi-center, randomized trial that seeks to validate Provista’s blood based biomarker panel assay in conjunction with imaging to differentiate benign breast lesions from invasive cancers. This multi-center trial is a follow-up to Provista’s 001 trial that recruited 351 women under the age of 50 with suspicious lesions thus, bringing Provista’s collective prospective clinical trial enrollment to 1,371 patients to date.

“This is a ‘first of its kind’ study of randomized, prospective trials that demonstrate the utility of well-established proteomic biomarker panels in the early detection of breast cancer,” said David Reese, PhD, CEO and President of Provista. “Our robust data gives the company extreme confidence in the ability of Provista’s protein biomarker assay to contribute to early cancer detection.”

To evaluate whether Provista’s blood test could aid in the detection of breast cancer, patients were prospectively enrolled in a randomized trial at 12 breast cancer centers across the United States. A small quantity of blood was drawn from patients to analyze several protein biomarkers and their expression patterns were evaluated by a proprietary algorithm to yield a unique protein signature. The goal of the

study is to determine whether a collection of biomarkers identified by Provista's test can differentiate malignant from benign tumors.

"We are extremely excited to be the first company to market this technology which offers a precise solution for breast cancer detection," said Dr. Christa Corn, MD, Medical Director of Provista.

According to the American Cancer Society, nearly 233,000 women will be diagnosed with breast cancer in the U.S. annually. Approximately 40,000 deaths occur from breast cancer every year. However, according to the American Cancer Society if detected early, breast cancer can be treated effectively. While biomarkers are often used to augment detection of various cancers, definitive biomarkers from breast cancer have remained elusive.

### **About Provista**

Provista Diagnostics is a privately held molecular diagnostics company focused on developing and commercializing a new generation of proprietary blood-based proteomic diagnostic, prognostic and monitoring tests designed to address the unmet needs in women's cancer, such as breast and gynecologic cancers. Provista Diagnostics' state-of-the-art, high-complexity clinical laboratory is accredited by the College of American Pathologists (CAP) and with the Clinical Laboratory Improvement Amendments (CLIA).

Additional information about Provista Diagnostics is available at [ProvistaDx.com](http://ProvistaDx.com)

Information about Provista Diagnostics' clinical trials is available at [ClinicalTrials.gov](http://ClinicalTrials.gov)

### **Safe Harbor Statement**

Statements contained in this communication not relating to historical facts are forward-looking statements that are intended to fall within the safe harbor rule for such statements under the Private Securities Litigation Reform Act of 1995. The information contained in the forward-looking statements is inherently uncertain, and Provista's actual results may differ materially due to a number of factors, many of which are beyond Provista's ability to predict or control, including among others, viability and effectiveness of our sales approach and overall marketing strategies, the outcome of development or regulatory review of our products, commercial success or acceptance by the medical community, competitive responses, our ability to raise additional capital, and the ability to successfully file a registration statement with the SEC. These forward-looking statements are subject to known and unknown risks and uncertainties that could cause actual events to differ from the forward-looking

statements. Provista operates in a highly competitive and rapidly changing business and regulatory environment, thus new or unforeseen risks may arise. Accordingly, investors should not place any reliance on forward-looking statements as a prediction of actual results. Except as is expressly required by the federal securities laws, Provista undertakes no obligation to update or revise any forward-looking statements, whether as a result of new information, changed circumstances or future events or for any other reason.

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