



## **Provista Diagnostics Announces First Patient Enrolled in Prospective, Proof-of-Concept Study of its Protein Biomarker Blood Test to Assess Presence of Breast Cancer**

**NEW YORK, NY** – May 19, 2014 – Provista Diagnostics, Inc., a molecular diagnostics company developing and commercializing proteomic-based diagnostic, prognostic and monitoring tests for cancers affecting women, today announced that the first patient has been enrolled in the company’s 500-patient prospective study of an advanced version of its proteomic breast cancer assay. The assay will measure several protein biomarkers that can be obtained from a small blood sample, with the goal of developing a laboratory test that can assess, in conjunction with standard imaging and the physician’s clinical evaluation, the presence of breast cancer.

This trial will enroll patients; aged 25-75 with suspicious breast masses, at approximately 10 well-known breast cancer centers across the United States. The goal of the study is to determine whether Provista’s biomarkers can distinguish benign lesions from breast cancer in these patients. A small blood sample will be drawn from patients who will be prospectively enrolled in a randomized manner.

“In keeping with Provista’s commitment to the early detection of women’s cancers, we are conducting an unusually rigorous study using Provista’s breast cancer biomarkers,” said David Reese, PhD., President and CEO. “We are fortunate to have the support of so many high quality breast cancer centers involved in this important trial.”

According to the American Cancer Society, nearly 233,000 women will be diagnosed with breast cancer in the U.S. in 2014. Approximately 40,000 deaths occur from breast cancer each year,. While biomarkers are often used to augment detection in various cancers, definitive markers for breast cancer have remained elusive.

“It is the goal of this trial to confirm the ability of protein-based biomarkers in radiologic assessment of breast masses,” said Sherri Borman, PhD., HCLD, Vice President of Laboratory Operations and Laboratory Director. “The substantial experience of our lab in working with complex clinical laboratory procedures, including development of novel protein based assays, will be invaluable to ensure the highest quality data from this trial.”

### **About the Study**

This prospective study will recruit 500 women, 25 to 75 years of age with a higher risk for breast cancer, as determined by a BI-RAD assessment of 3 or 4. A small quantity of blood will be analyzed for the presence of certain protein biomarkers that will be evaluated by a proprietary algorithm to define a numerical score that differentiates malignant from benign disease.

## **About Provista Diagnostics, Inc.**

Provista Diagnostics, Inc. is a privately held molecular diagnostics company focused on developing and commercializing blood based, proprietary diagnostic, prognostic and monitoring tests for cancers affecting women, including breast, ovarian and other gynecologic malignancies. Tests are performed in Provista's high complexity clinical laboratory, which is licensed in 49 states and is certified by the Centers for Medicare & Medicaid Services (CMS) to be compliant with the Clinical Laboratory Improvement Amendments (CLIA). Additional information about Provista Diagnostics is available at [www.provistadx.com](http://www.provistadx.com).

Information about ongoing trials is available at [www.clinicaltrials.gov](http://www.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.

## Contact

David R. Holmes  
Provista Diagnostics, Inc.  
HolmesD@ProvistaDx.com  
(212) 202-3170

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