Provista Diagnostics Offers Hope for the Early Detection of Breast Cancer in Women with Dense Breasts

Data presented at the 2015 American Society of Clinical Oncology Breast Cancer Symposium received overwhelming support from Key Opinion Leaders involved in the clinical trials

NEW YORK, NY – September 29, 2015: Provista Diagnostics, Inc. today announced that the data from two prospective, randomized, multi-center clinical studies, evaluating a novel blood-based combinatorial protein biomarker assay, received overwhelming support from Key Opinion Leaders at the 2015 American Society of Clinical Oncology (ASCO) Breast Cancer Symposium, held September 25 - 27, 2015 in San Francisco, California. “We are grateful to these distinguished physicians for their support,” said David Reese, Ph.D., President and CEO of Provista. “With their enthusiasm to use a blood-based test such as ours, Videssa™ Breast will be widely recognized for its clinical utility in women who are currently difficult to diagnose.”

The detection of breast cancer relies on the visual interpretation of radiological imaging findings. Unfortunately, breast density can affect the visualization of small tumors, requiring additional imaging, such as ultrasound and/or MRI. Ultimately, an indeterminate finding on imaging often leads to a tissue biopsy in order to confirm the presence or absence of cancer. With over 1.7 million biopsies performed annually and less than 20% yielding a positive finding (cancer), this results in increased anxiety for the patient and significant healthcare costs.

To address this unmet need, Provista Diagnostics developed a simple blood-based diagnostic test, Videssa™ Breast, which can be used in combination with imaging to differentiate benign from breast cancer lesions, thus reducing the number of further diagnostic procedures and benign biopsies performed. Multiple proteomic biomarkers are incorporated into the Videssa™ Breast test and have shown their ability to detect the presence of breast cancer at a very early stage in multiple prospective clinical trials (ID NCT02078570 and NCT01839045).

“Currently, Videssa™ Breast has been studied in 848 women and the data consistently demonstrates the benefits of the test,” said Dr. Christa Corn, MD, Medical Director of Provista. “Women and physicians need clarity with these difficult-to-detect breast lesions. Our technology provides a real-time, quantitative actionable result, which is critical in order to detect breast cancer at its earliest stage with high confidence.”

“Our robust clinical data reinforces our confidence in Videssa™ Breast,” adds Dr. Reese. “With the ability to distinguish benign from breast cancer lesions using a simple blood sample, this represents a significant advancement in breast cancer detection; particularly in difficult to diagnose lesions and patients with dense breasts.”
Provista’s presentations at the ASCO Breast Cancer Symposium:

BOARD F3: Abstract 31; Provista 002 Prospective Randomized Trial Utilizing a Combinatorial Protein Biomarker Assay in conjunction with imaging to detect breast cancer from patients with imaging findings age 25-75.

BOARD E9: Abstract 27; Age-related variations: A retrospective analysis of 848 prospectively collected patient samples to determine the benefit of combining combinatorial protein biomarker assay for risk assessment in women with dense breast.

About Provista Diagnostics, Inc.
Provista Diagnostics is a privately held molecular diagnostics company focused on developing and commercializing a new generation of proprietary blood-based 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 certified by the Centers for Medicare and Medicaid Services (CMS) to be compliant with the Clinical Laboratory Improvement Amendments (CLIA).

Additional information about Provista Diagnostics is available at ProvistaDx.com
Information about Provista Diagnostics’ clinical trials is available at ClinicalTrials.gov

About the American Society of Clinical Oncology (ASCO) Breast Cancer Symposium
The Breast Cancer Symposium is a two-and-a-half-day educational forum filled with opportunities for oncologists and other members of the breast cancer care community to meet for discussion of both systemic and local-regional disease management in an intimate setting. The Symposium consists of educational sessions that highlight clinically relevant translational science that affects current breast cancer management. For more information about ASCO Breast Cancer Symposium: breastcasym.org.

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