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Provista Diagnostics Completes Enrollment of its 001 Prospective Study of Protein-Based Biomarker Blood Test to Aid in Detection of Breast Cancer

Prospective, Randomized, Multi-Center Study for Breast Cancer Detection in 351 Female Patients with Suspicious Breast Lesions

New York, NY – July 15, 2014 – Provista Diagnostics, Inc., a personalized medicine company focused on developing and commercializing proprietary blood-based prognostic, diagnostic, and monitoring tests for cancers affecting women, today announced that the final patient has been enrolled in a prospective, blinded, randomized study of Provista's proteomic breast cancer detection test. The 001 study is designed to utilize Provista's proprietary blood test in conjunction with standard of care to help assess the presence of breast cancer in patients with suspicious breast lesions.

The trial enrolled 351 women, 25 to 49 years of age who were classified under the Breast Imaging-Reporting and Data System (BI-RADS®) Assessment Category 3 or 4. BI-RAD® 3 patients are defined as women with lesions that are probably benign and Assessment Category 4, defined as suspicious for malignancy. "The distinction of BI-RADS® 3 and 4 is important for women as it usually defines a course of treatment that usually includes either biopsy or 6-month follow-up," said Dr. Christa Corn, MD., Medical Director of Provista Diagnostics. Women under the age of 50 were specifically enrolled due to the limitations of current detection modalities for women in this age group. Additionally, cancers found in women under the age of 50 have been shown to be more aggressive. "Provista's test was designed to aid in detection for this difficult to diagnose population," added Dr. Corn. Provista's test is used in conjunction with a BI-RADS® 3 or 4 classification, which is based on suspicious anatomical changes, by providing further evidence as to the biochemical signature of the individual patient. By providing both biochemical and anatomic information to physicians, the goal is to precisely inform whether the patient should undergo biopsy, further imaging studies or a 6-month follow-up. "The BI-RADS® 3 or 4 categories

are critical decision points in breast cancer detection, where a classification of 4 is usually biopsied, and often a 3 is assessed in a 6 month follow up," noted Dr. Corn.

To evaluate whether Provista's blood test could aid in the detection of breast cancer, patients were prospectively enrolled in a randomized trial at 10 breast cancer centers across the United States. A small quantity of blood was drawn from patients to analyze certain protein biomarkers and evaluated by a proprietary algorithm. The goal of the study is to determine whether a collection of biomarkers identified by Provista's test can differentiate malignant from benign tumors.

"The completion of enrollment of this study of our proteomic-based breast cancer detection test represents a major milestone for Provista as we continue to advance its development toward commercialization," said David Reese, PhD, President and CEO of Provista. "I am very grateful to our centers and collaborators for their support and, most of all, to the 351 patients who participated in this study with the goal of improving the detection of breast cancer. Provista and its collaborators look forward to reporting the results of this study in a scientific publication and at a major breast cancer symposium."

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. While biomarkers are often used to augment detection of various cancers, definitive biomarkers for 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
Information about Provista Diagnostics' clinical trials is available at ClinicalTrials.gov

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