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Veracyte, Inc. to Acquire Allegro Diagnostics, Accelerating Entry Into Pulmonology Market

-- Plans to Launch Lung Cancer Test In the Second Half of 2015, With Meaningful Revenue Expected in 2017 --
-- Conference Call and Webcast Today at 5 p.m. ET --

SOUTH SAN FRANCISCO, Calif., Sept. 4, 2014 /PRNewswire/ -- Veracyte, Inc. (Nasdaq: VCYT), a molecular diagnostics company pioneering the field of molecular cytology, today announced an agreement to acquire Allegro Diagnostics Corp. based in Maynard, Mass., for $21.0 million, comprised of $7.8 million in cash and $13.2 million in Veracyte common stock. Allegro is a privately held company focused on developing genomic tests to improve the preoperative diagnosis of lung cancer.

Veracyte plans to commercially launch Allegro's lead lung cancer test in the second half of 2015, with meaningful revenue expected in 2017.

Allegro's lung cancer test is designed to help physicians determine which patients with lung nodules who have had a non-diagnostic bronchoscopy result are at low risk for cancer and can thus be safely monitored with CT scans rather than undergoing invasive procedures. The gene expression test uses Allegro's proprietary "field of injury" genomic technology platform to circumvent the traditional challenge of obtaining accurate lung nodule samples for testing, without surgery or other invasive, risky and expensive procedures.

"With Allegro and its novel, clinically validated lung cancer test, we plan to accelerate our entry into the pulmonology market, enabling us to improve care for patients with lung nodules while creating long-term growth opportunities," said Bonnie H. Anderson, Veracyte's president and chief executive officer. "Allegro is a natural fit for us and we believe this move further establishes our leadership in molecular cytology, using genomics to resolve diagnostic ambiguity preoperatively and thus spare patients from unnecessary invasive procedures and reduce associated healthcare costs."

Allegro's technology detects molecular changes that occur throughout the respiratory airways in response to smoking - the cause of almost all lung cancers - and that are correlated with disease. These changes can be detected in a gene expression signature from cytologically normal airway cells and indicate the presence of malignancy or disease processes from distant sites in the lung. The lung cancer test is performed on cytology samples obtained through bronchoscopy, a minimally invasive procedure that enables a physician to access airways in the lung. The molecular classifier's performance has been established in two prospective, multicenter clinical validation studies, involving 25 centers and nearly 1,000 patients.

"We are excited for our lead test to become available to patients, helping to reduce unnecessary diagnostic surgeries and other procedures among the hundreds of thousands of patients with lung nodules who undergo bronchoscopies each year in the U.S to rule out cancer," said Michael D. Webb, president and chief executive officer of Allegro Diagnostics. "We believe Veracyte is uniquely poised to commercialize and gain reimbursement for our test, given the rapid success the company has achieved with its Afirma® solution in endocrinology."

About Lung Cancer Diagnosis

Lung cancer is the leading cancer killer in the U.S., with an estimated 225,000 new cases diagnosed and approximately 160,000 deaths caused by the disease each year. Recent guidelines recommend annual CT screening for high-risk patients, with an estimated eight million Americans falling into this category based on smoking history and age. Among the approximately 250,000 bronchoscopies currently performed each year in the U.S. to evaluate lung nodules - a potential sign of cancer - up to 40 percent produce non-diagnostic results, based on pathology. Approximately half of these patients undergo surgery or other invasive procedures to obtain a diagnosis. Data show that approximately 40 percent of lung nodule patients who undergo surgery prove to have benign nodules. Thus, a better way to risk-stratify patients at high risk of lung cancer could help determine which patients can be safely followed with CT scans versus invasive procedures.

Conference Call/Webcast Details

Veracyte will host a conference call and webcast today at 5 p.m. Eastern Time to discuss the company's acquisition of Allegro Diagnostics. The webcast and subsequent replay may be accessed by visiting Veracyte's website at

http://investor.veracyte.com. Please connect to the company's website at least 15 minutes prior to the webcast to ensure adequate time for any necessary software download. Alternatively, please call (855) 541-0980 (U.S.) or (970) 315-0440 (international) to listen to the conference call. The conference ID number for the call is 97439649. Please dial in approximately 10 minutes prior to the call. The webcast will be available on the company's website approximately two hours following completion of the call for 14 days.

About Veracyte

Veracyte (Nasdaq: VCYT) is pioneering the field of molecular cytology, focusing on genomic solutions that resolve diagnostic ambiguity and enable physicians to make more informed treatment decisions at an early stage in patient care. By improving preoperative diagnostic accuracy, the company aims to help patients avoid unnecessary invasive procedures while reducing healthcare costs. Veracyte's first commercial solution, the Afirma® Thyroid FNA Analysis, provides a comprehensive approach for assessing thyroid nodules, centered on the proprietary Gene Expression Classifier (GEC) to resolve ambiguity in diagnosis. Each year, of the more than 525,000 thyroid nodule FNAs performed in the U.S., approximately 115,000 patients undergo diagnostic thyroid surgery, with 70% to 80% of nodules proving benign and thus the surgery unnecessary. Veracyte commercially launched Afirma in January 2011. As of June 30, 2014, the company has received nearly 115,000 FNA samples for evaluation using Afirma and has performed over 20,000 GECs to resolve indeterminate cytopathology results. Backed by multiple, peer-reviewed, published studies and included in leading medical guidelines, Afirma is covered by Medicare and major commercial payers, which collectively represent more than 135 million covered lives. Afirma is marketed and sold through a global co-promotion agreement with Genzyme Corporation, a subsidiary of Sanofi. Veracyte intends to expand its molecular cytology franchise to other clinical areas and is in product development for its first product in pulmonology. For more information, please visit www.veracyte.com.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including statements relating to the company's belief that the acquisition of Allegro will accelerate Veracyte's entry into the pulmonology market and allow it to improve patient care while creating long-term growth opportunities, the company's plans to launch Allegro's lung cancer test in the second half of 2015 and its beliefs regarding when it expects to derive meaningful revenue from the test, the company's beliefs regarding the benefits of its tests and Allegro's tests to physicians, patients and payers, and the company's intent to expand its molecular cytology business into other clinical areas. Forward-looking statements involve risks and uncertainties, which could cause actual results to differ materially, and reported results should not be considered as an indication of future performance. These risks and uncertainties include, but are not limited to: our ability to close the acquisition; our limited operating history and history of losses; our ability to increase usage of and reimbursement for Afirma and any future products we may develop or sell, including the Allegro lung cancer test; our ability to continue our momentum and growth; our dependence on a few payers for a significant portion of our revenue; the complexity, time and expense associated with billing and collecting from payers for our test; laws and regulations applicable to our business, including potential regulation by the Food and Drug Administration or other regulatory bodies; our dependence on strategic relationships and our ability to successfully convert new accounts resulting from such relationships; our ability to develop and commercialize new products and the timing of commercialization, including our ability to successfully commercialize the Allegro lung cancer test; our ability to achieve sales penetration in complex commercial accounts; the occurrence and outcome of clinical studies; the timing and publication of study results; the applicability of clinical results to actual outcomes; our inclusion in clinical practice guidelines; the continued application of clinical guidelines to our products; our ability to compete; our ability to expand into international markets; our success integrating Allegro into our business; our ability to obtain capital when needed; and other risks set forth in the company's filings with the Securities and Exchange Commission, including the risks set forth in the company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2014. These forward-looking statements speak only as of the date hereof and Veracyte specifically disclaims any obligation to update these forward-looking statements.

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