

Allegro Diagnostics Completes Patient Enrollment in 1,320-Patient AEGIS II Study for Improved Detection of Lung Cancer

Maynard, Mass.– Allegro Diagnostics today announced the completion of enrollment in the 1,320-patient AEGIS II (Airway Epithelium Gene Expression In the Diagnosis of Lung Cancer) clinical trial, which is evaluating the diagnostic ability of the BronchoGen™ genomic test used in conjunction with bronchoscopy to detect early signs of lung cancer compared to the ability of bronchoscopy alone. BronchoGen is Allegro Diagnostics' lead genomic test, and it is built upon the Company's molecular testing platform that utilizes gene expression of normal epithelial cells in the respiratory tract to detect early signs of lung cancer. Data from the AEGIS II study are expected in mid-2013.

“The completion of patient enrollment in AEGIS II is an important milestone for Allegro Diagnostics. We are now evaluating BronchoGen in over 2,000 patients and in the process have generated the largest prospective clinical dataset for a lung cancer molecular diagnostic,” said Michael D. Webb, President and Chief Executive Officer of Allegro Diagnostics. “This trial significantly advances our product development strategy for the BronchoGen genomic test, which is rapidly approaching commercialization. Over half of the more than 300,000 bronchoscopies performed annually in the United States in patients at high risk for lung cancer result in an inconclusive cancer diagnosis. We believe that BronchoGen has the potential to improve dramatically upon the current diagnostic standard of care.”

“We are very appreciative of our investigators' diligence and grateful to the patients who have participated,” added Duncan Whitney, Ph.D., Senior Vice President, Research, Development and Technical Operations and the study's director. “While results from AEGIS II are expected in 2013, later this year we will announce data from the 730-patient AEGIS I trial, which was designed to demonstrate the diagnostic accuracy of BronchoGen and serve as the basis to make this potentially valuable test available to patients and clinicians.”

About the AEGIS II Trial

The Airway Epithelium Gene Expression in the Diagnosis of Lung Cancer II (AEGIS II) trial is a prospective, multi-center study designed to evaluate the BronchoGen™ genomic test in conjunction with bronchoscopy to aid in the diagnosis of lung cancer in current or former cigarette smokers. Endpoints include the sensitivity, specificity, negative predictive value and positive predictive value of BronchoGen for identifying patients with malignancy. The 1,320-patient trial is being conducted at twenty-two centers throughout the United States. Data from the study are expected in mid-2013. To learn more about the AEGIS II clinical trial, please visit www.clinicaltrials.gov [1].

About the Allegro Platform

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Allegro Diagnostics' molecular testing platform utilizes gene expression of normal epithelial cells in the respiratory tract to detect early signs of lung cancer. The "field of injury" principle on which the platform is based refers to the common molecular response that occurs throughout the respiratory tract in current and former smokers with lung cancer. These changes can be detected in a gene expression signature from non-malignant airway cells and indicate the presence of malignancy remotely in the lung. Allegro has applied this platform to generate multiple product candidates.

About Allegro Diagnostics

Allegro Diagnostics is a molecular diagnostics company focused on the development and commercialization of innovative genomic tests for the diagnosis, staging and informed treatment of lung cancer and other lung diseases. Allegro has developed a molecular testing platform that utilizes a genomic signature to detect early signs of lung cancer in current and former smokers. The Company's lead product is the BronchoGen™ genomic test for use in combination with standard bronchoscopy for the diagnosis of lung cancer. www.allegrodx.com [2]

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Links:

[1] <http://www.clinicaltrials.gov>

[2] <http://www.allegrodx.com>