



Allegro Diagnostics Receives \$2.8 Million SBIR Grant from National Cancer Institute

Grant Will Support Clinical Development of BronchoGen^(TM), Other Allegro Products

BOSTON, Oct. 22 /PRNewswire/ -- Allegro Diagnostics, a leader in the field of molecular diagnostics for lung cancer, has announced that its clinical study for BronchoGen^(TM), a diagnostic test for patients suspected of having lung cancer, will receive up to \$2.8 million in funding for a Phase I/II Fast Track Small Business Innovation Research (SBIR) grant from the National Cancer Institute (NCI). This groundbreaking clinical study is enrolling up to 800 patients at 12 sites in the U.S. If successful, BronchoGen(TM) would be a first in class, novel test in an area of significant unmet medical need.

"Bravo to Allegro Diagnostics," said Laurie Fenton Ambrose, President & CEO of Lung Cancer Alliance (LCA), the only national organization providing patient support and advocacy solely to those living with or at risk for the disease, "for making earlier, more accurate diagnosis of suspected lung cancer a research a priority. It is our hope that this trial will prove successful and ultimately bring important benefits to both doctors and patients - something long overdue. We look forward to closely monitoring the progress of this research and team of world class leaders."

"The elegant technology developed by Allegro scientists could be a very valuable piece of our quest to diagnose lung cancer as early and accurately as possible, and in a cost effective manner. I look forward to the study," commented Steve Shapiro, MD, Professor and Chairman of the Department of Medicine at University of Pittsburgh.

BronchoGen^(TM) uses easily accessible cells lining the airway (bronchial epithelial cells) obtained during bronchoscopy and analyzes their RNA to measure gene expression levels. Allegro's scientific team has found that specific sets of genes are over- and under-expressed in current or former smokers with lung cancer as compared to those without lung cancer. This finding was validated in a 164 patient study published in Nature Medicine in March, 2007. Importantly, the BronchoGen^(TM) approach does not require an actual tissue sample from a suspicious nodule or lesion, which often must be accessed through highly invasive procedures that pose significant risks to the patient.

Bronchoscopy is one of the most common diagnostic modalities used to assess patients for suspicion of lung cancer. Performed over 300,000 times a year in the U.S. in such patients, bronchoscopy has relatively low sensitivity for detecting disease in those patients who have it, leading to a high number of false negative results. Guidelines from the American College of Chest Physicians state that when a bronchoscopy is non-diagnostic or negative and suspicion of lung cancer remains, a clinician should pursue additional diagnostic procedures to assess the patient's status.

"The NCI support for our trial is highly encouraging news for current or former smokers at risk for lung cancer, and will propel the development of BronchoGen^(TM). It will also help Allegro Diagnostics extend its scientific platform into other areas," said Dan Rippey, President & CEO of Allegro. "Lung cancer patients generally have a very poor prognosis because most are diagnosed with late stage

disease. BronchoGen(TM) may help clinicians to detect disease earlier and reduce unnecessary medical procedures in those patients who do not have lung cancer."

"The NCI grant recognizes the importance of developing new and innovative approaches to the diagnosis and treatment of lung cancer," said Jerome Brody, MD, chief scientific officer, co-founder of Allegro Diagnostics and an author on the Nature Medicine study. "The grant will accelerate Allegro Diagnostics' current clinical trial aimed at validating BronchoGen as an early lung cancer diagnostic tool and will assist in developing a series of additional genomic tests that could help lessen the human toll of the leading cause of cancer death in the US and the world."

"This test could be a real breakthrough," said Frank Hull, MD, of Broward Health in Fort Lauderdale, Florida. "My patients are very anxious once they are told they have a lung nodule that could be cancer. Particularly in small lung nodules below the resolution of PET scanning and difficult to accurately biopsy, this test could result in earlier treatment in patients with lung cancer. In patients with benign nodules this could save two years of anxiety, which is the usual time period that we follow these lung nodules with serial imaging before we ascertain them as benign."

"The development of technologies that can aid in the accurate diagnosis of lung cancer based on analysis of (bronchial) samples is likely to result in less discomfort to patients and may help bring down costs associated with diagnostic testing," said Ali Andalibi, Ph.D., Program Director with the National Cancer Institute.

About Lung Cancer

According to the American Cancer Society, more than 220,000 new cases of lung cancer are diagnosed each year in the U.S., and more than 150,000 deaths occur annually from the disease. Lung cancer is the leading cause of cancer death in the industrialized world, responsible for more than 1.3 million deaths per year worldwide. In the U.S., lung cancer kills more people than colon, breast, prostate, and ovarian cancers combined. While lung cancer can be cured by surgery if caught in the early stages, 65-80% of lung cancer patients present with late stage disease. The five-year survival rate for lung cancer patients is roughly 15%, a rate that has remained unchanged for several decades.

About Allegro Diagnostics

Allegro Diagnostics was founded in 2006 to develop and commercialize molecular diagnostics in lung cancer and other pulmonary diseases using proprietary gene expression technology originating within the Pulmonary Center at the Boston University School of Medicine. The company's initial focus is on earlier stage, more accurate diagnosis of suspected lung cancer. Allegro Diagnostics is privately funded by Kodiak Venture Partners, Catalyst Health Ventures, and Boston University. For more information, visit the website of Allegro Diagnostics at: www.allegrodx.com.

About Kodiak Venture Partners

Founded in 1999, Kodiak manages three funds totaling \$676M and targets companies in North America. Kodiak focuses on seed and early stage investments in emerging communications/wireless, semiconductor/equipment, software/services, internet/new media, and life technology companies. Kodiak's partners are successful high-technology business entrepreneurs who take a hands-on approach to building market leaders. Previous Kodiak investments have included ALIS Corporation,

Fluxion Biosciences, and Groove Mobile. For more information on Kodiak Venture Partners, visit: www.kodiakvp.com.

About Catalyst Health Ventures

Catalyst Health Ventures is an early-stage venture capital firm targeting technology solutions applied within the health care and life science industries. At the core of its strategy is a committed, hands-on approach to working with management and syndicate partners to build successful companies. Catalyst's disciplined investment process leverages both intellectual and financial capital to originate deals, cultivate opportunities, and realize the full potential of emerging ventures in the health care and life science marketplace. For more information on Catalyst Health Ventures, visit: www.catalysthealthventures.com.

SOURCE: Allegro Diagnostics