



FOR IMMEDIATE RELEASE

PRESS CONTACT:

Susan O'Neil
River City Studio
816.872.3824
susano@rivercitystudio.com

ONCIMMUNE RELEASES TEST THAT AIDS IN EARLY DETECTION OF LUNG CANCER

*Biotechnology Company furthers its Mission for Early Cancer Detection by Announcing the Regional Release of **EarlyCDT–Lung™**, a Blood Test that Can Detect the Earliest Stages of Lung Cancer*

De Soto, Kan. – August 25, 2009 – In the ongoing effort to improve the outcome of patients diagnosed with lung cancer, Oncimmune LLC introduces **EarlyCDT–Lung™**, a blood test that aids physicians in early detection of the disease. Categorized as a high-complexity test under CLIA guidelines, the **EarlyCDT–Lung** test is performed exclusively at Oncimmune's CLIA registered laboratory. The laboratory procedure utilizes multiple high-precision liquid handling robots and other instrumentation to produce an accurate test result. **EarlyCDT–Lung** was developed through biomedical technology identified in the laboratories of John Robertson, M.D., Professor of Surgery at Nottingham University, England, and Chief Scientific Officer of Oncimmune LTD^{1,2}. Over the past 15 years, 25 million dollars have been invested into **EarlyCDT–Lung**. Samples from more than 80,000 individuals (both with cancer and without), totaling nearly 8 million individual results, have been devoted to the research and development phase of this test.

EarlyCDT–Lung measures a panel of six autoantibodies each selected for their involvement in the development of lung cancer. The test detects the body's immune response in the form of antibodies to antigens, which are produced by solid-tumor cancer cells. In healthy individuals, the immune system does not produce antibodies against normal tissue antigens. When cancer develops, cancer cells produce antigens that are abnormal or in some way modified from those found in normal tissue. The immune system detects these antigens and reacts by producing an abundance of autoantibodies that circulate in the bloodstream. As these autoantibodies form and circulate in the body during stages I and II, the earliest stages of lung cancer, their measurement signifies the presence of cancerous cells, indicating that a tumor exists. Used in conjunction with diagnostic imaging, **EarlyCDT–Lung** has the potential to identify lung cancer at a very early stage, when treatment can be most successful. The test is primarily recommended for individuals who are at higher risk of lung cancer, such as long-term smokers, ex-smokers and those exposed to environmental factors such as asbestos, radon and/or radioactive substances.

"After many years of developing and refining this autoantibody test, I am very proud of what we have achieved. The test is highly reproducible, and I believe it will lead to significant improvements in outcome for a substantial number of those diagnosed with early stage lung cancer," said John Robertson, M.D., founder and Chief Scientific Officer, Oncimmune LTD.

Pricing and Availability

EarlyCDT–Lung is among the more moderately priced laboratory tests prescribed by physicians. At this time, insurance carriers do not cover **EarlyCDT–Lung**, although individuals are able to pursue this option with their insurance company on an individual basis or through their HSA (health savings account) or FSA

(flexible spending account). The retail list price of **EarlyCDT–Lung** is \$500. The regional release price of the test is \$200. Through the regional release, the test is available through five Kansas pulmonologist and family care physician groups, three of which are in the Kansas City Metro Area. The test is also offered by additional physicians located throughout the Midwest and Southeast regions. For a list of providers in your area, please call (888) 583-9030. The test is exclusively performed at Oncimmune’s De Soto, Kansas, laboratory, which complies with CLIA guidelines enacted under the Clinical Laboratory Improvement Amendments of 1988. Oncimmune plans a full national release of **EarlyCDT–Lung** in 2010.

Lung Cancer

Lung cancer is responsible for 28 percent of all cancer-related deaths each year, a higher mortality rate than breast, colorectal, prostate, pancreatic and cervical cancer combined³. Medical science has developed a number of methods for earlier detection of many cancers, which is responsible in part, for an overall decline in cancer-related deaths. However, over the past 40 years, the mortality rate for lung cancer patients remains essentially unchanged⁴.

Approximately 219,000 people are diagnosed with lung cancer in the U.S. each year – including more than 103,000 women, of which, 50 percent have never personally smoked⁵. Lung cancer is responsible for roughly 160,000 deaths each year in the U.S.⁶. The prognosis for lung cancer patients is poor with roughly 85 percent of patients dying within five years of diagnosis, compared to 11 percent of breast cancer and less than one percent of prostate cancer patients⁷; however, when lung cancer is diagnosed in stage I, the survival rate increases to approximately 50 percent³. Currently, only 16 percent of lung cancer patients are diagnosed before the disease spreads to other parts of their bodies⁸.

The low survival rate of lung cancer patients is related, in part, to inadequate early detection. The non-specific symptoms of lung cancer, including shortness of breath, consistent chest pain and other indicators, have also been a contributing factor as they are often misconstrued and associated with varied illnesses.

Early Detection

It is evident through randomized controlled trials of breast, cervical and colorectal cancers that early detection improves prognosis for survival and lowers mortality rates. For other types of cancers such as gastric and lung, additional evidence from nonrandomized studies supports the suggestion that early diagnosis leads to improved survival. Computerized tomography, CT, studies also confirm that lung cancer patients experience greatly increased survival rates when the cancer is identified at stages I or II⁹. Currently, there is no accepted method of early detection for lung cancer, defined as stage I or II, when time allows for surgical removal with a reasonable chance of improved prognosis (75 percent or higher)¹⁰. The **EarlyCDT–Lung** test detects cancer developing in the earliest stages of the disease and is therefore expected to significantly advance early detection of lung cancer and subsequently improve patient prognosis.

“It is very good news that a simple blood test with the potential to really improve prognosis for lung cancer is now available. Over the next few years we will continue to work on advancing this test, whilst at the same time expanding the remit of the test to cover the early detection of additional cancers. The dedication of the staff and the support of our shareholders and Scientific Advisory Board members have been of great importance. The cooperation of these eminent people has been invaluable as we work toward the goal of reducing the cancer mortality rate,” said Geoffrey Hamilton-Fairley, Executive Chairman, Oncimmune LTD.

About Oncimmune

Oncimmune LLC, founded in 2006, is an industry leader in early cancer detection. The company is committed to advancing early cancer detection through proprietary autoantibody assay technologies based on biological technology identified by John Robertson, M.D., Professor of Surgery at Nottingham University, England, and Chief Scientific Officer of Oncimmune, LTD. Ongoing research and development

is conducted by Oncimmune under the direction of Professor Robertson. The company's mission is to develop early cancer detection tests to identify more than 90 percent of solid-tumor cancers, which make up 70 percent of all cancers including lung, breast, colorectal, prostate, stomach, pancreatic and ovarian. All testing is performed exclusively within Oncimmune's CLIA registered clinical laboratory located in De Soto, Kansas. Oncimmune LLC is a wholly owned subsidiary of Oncimmune LTD. Oncimmune LTD owns a portfolio of patents, including Patent No. 7,402,403 and 7,205,117, with five others currently filed and under review. For more information please visit www.oncimmune.com.

About *EarlyCDT–Lung*TM

EarlyCDT–Lung is a blood test that detects the body's immune response in the form of antibodies to antigens produced by solid-tumor cancer cells. Autoantibodies form in the body during stages I and II; the earliest stages of cancer. The immune system reacts to these selected antigens by producing a biological marker in the form of autoantibodies that freely circulate in the bloodstream. Precise measurement of autoantibodies provides an early indication that a tumor exists, enabling accurate detection of cancerous cells. Through a refined and automated assay platform, the ***EarlyCDT–Lung*** test utilizes a panel of six antigens individually selected for their involvement in the development of cancerous tumors.

Oncimmune LLC and ***EarlyCDT*** are trademarks or registered trademarks of Oncimmune LTD.

All other trademarks are the property of their respective owners.

CLIA, Clinical Laboratory Improvement Amendments of 1988, was enacted by Congress to ensure all U.S. laboratories meet standards of accuracy, reliability and timeliness. For more information please visit www.cms.hhs.gov/CLIA.

###

¹ CJ Chapman, et al. Autoantibodies in Breast Cancer: Their Use as an Aid to Early Diagnosis. *Annals of Oncology* 2007;18(5):868-873.

² CJ Chapman, et al. Autoantibodies in Lung Cancer - Possibilities for Early Detection and Subsequent Cure. *Thorax* 2007;63(3):228-233.

³ American Cancer Society, www.cancer.org.

⁴ U.S. Department of Health and Human Services.

⁵ JD Patel. Lung cancer in women. *Journal of Clinical Oncology* 2005;23(14):3212-3218.

⁶ American Cancer Society. The lung cancer treatments guidelines for patients. 2008; version IV:7.

⁷ World Health Organization. Deaths by cause, sex and mortality stratum in WHO regions. *The World Health Report* 2004.

⁸ National Cancer Institute. <http://www.cancer.gov/>.

⁹ American Cancer Society. *Cancer Facts and Figures*. 2008:14-15.

¹⁰ American Thoracic Society and European Respiratory Society. Pretreatment Evaluation of Non-Small-Cell Lung Cancer. *American Journal of Respiratory and Critical Care Medicine* 1997;156(1):320-332.