National Jewish Health, the Nation's Premier Respiratory Hospital, Announces Lung Cancer Screening Trial Using Blood Test and CT

Trial to evaluate clinical benefit of EarlyCDT®-Lung blood test use in conjunction with low dose CT

DENVER and DeSoto, Kansas – May 1, 2012 - National Jewish Health (NJH), the # 1 respiratory hospital in the United States, today announces the initiation of a lung cancer screening trial that evaluates the use of a blood test, known as *Early*CDT-Lung, in conjunction with low dose CT to determine the clinical value added by the blood test when compared to CT screening alone, which was shown recently by the National Lung Screening Trial (NLST) [(1)] in the U.S. to reduce mortality by 20%. James Jett, M.D., a National Jewish Health lung cancer expert, will serve as the principal investigator for the study. Patient recruitment for the trial begins immediately. Those interested in participating can call 303.398.1911. (See eligibility requirements below - **How to take part in the trial**.)

The National Jewish Health trial will be a prospective trial combining low dose (radiation) CT screening and the *Early*CDT-Lung blood test to determine if the two together are better than either test alone when used in screening high risk individuals for lung cancer. Previous studies that led to the development and launch of the *Early*CDT-Lung blood test as a risk assessment tool for lung cancer were case control trials.

"Having watched the progress of the *Early*CDT-Lung test with interest over the past few years I am excited to be the Principal Investigator for the new study between CEAC (The Centre of Excellence for Autoimmunity in Cancer – Nottingham University, UK) and National Jewish Health being announced today. I reviewed the *Early*CDT-Lung validation data before launch and I also reviewed the performance of the first 1,000 commercial tests in the USA. These showed that the test performed as expected in the clinical setting and I presented this analysis at the World Lung Cancer Conference in Amsterdam last year. I believe the time is now right to explore extending the use of the test to population screening for high risk patients," said Jett.

The National Jewish Health study compliments the recently announced Scotland (UK) study of 10,000 high risk smokers which will determine the cost-effectiveness of using *Early*CDT-Lung as a primary screening tool. In the Scotland study, patients with a positive blood test result will have a follow up CT.

Jett was part of one of the first studies in the U.S. that looked at CT screening when he was at the Mayo clinic. The study ran from 1999 to 2004 on approximately 1,600 patients. At that time CT seemed to have the potential to detect early lung cancer, and many clinicians believed it would lead to a mortality benefit. The Mayo study showed that use of CT did lead to earlier cancers being detected. Mortality benefit has subsequently been shown to be a reality with the announcement of the large National Cancer Institute's NLST on more than 53,000 participants. Those results showed a 20% mortality benefit with CT screening when compared to standard chest X-ray. The next stage in the development of screening for lung cancer is to investigate what other tests in conjunction with CT can add to the clinical utility of CT alone. A simple biomarker test that would allow better identification and risk assessment of "at risk" patients is attractive as it has the potential to increase the number of early stage cancers diagnosed and improve cost-effectiveness of screening.

"The lung cancer community is constantly monitoring potential bio-markers in development and the few that have come to market. The *Early*CDT-Lung test has now been on the market for over two years and its performance may translate to the benefits I have described and it for this reason that I am delighted to be able to conduct this study. The study will screen 1,600 patients over 4 years and the first results are expected to be reported in 2014," said Jett.

According to Professor John Robertson, M.D., Director of CEAC, and Founder and Chief Scientific Officer of Oncimmune Ltd, the makers of *Early*CDT-Lung, "A randomised screening trial of this nature with a leading Lung Cancer Centre such as NJH will help validate *Early*CDT-Lung use as a screening tool. This combined with the large Scottish screening trial on 10,000 high risk smokers should provide sufficient data for accurate assessment of *Early*CDT-Lung both clinically and economically.

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 will I believe lead to significant improvement in prognosis for a substantial number of lung cancer sufferers. We are working

hard on bringing the next test for the early detection of breast cancer to the market within a year. We are also working on a number of similar tests for prostate, colon and ovarian cancer – a blood test to aid detection of all tumour cancers (70% of all cancer) is still the overriding objective of our work".

How to take part in the trial

Participants need to be 50-75 years of age, have a smoking history of at least 20 pack-years (equivalent to a pack a day for 20 years), and be a current or former smoker who quit fewer than 10 years ago. Those who have a history of cancer other than skin cancer, serious illness that limits their life expectancy to less than 5 years, or currently use oxygen to breathe are not eligible for the study.

Participants will receive both the EarlyCDT-Lung blood test and a low-dose CT scan at no charge. **Those interested in participating can call 303.398.1911.**

About Lung Cancer

Lung cancer is the world's leading cause of cancer-related mortality and the major source of cancer mortality in the US, killing about 160,000 people annually, more than breast, colon, and prostate cancer combined. Approximately 85% of patients with lung cancer remain undiagnosed until the disease is symptomatic and has reached an advanced stage. Early detection of lung cancer and diagnosis improves prognosis - the current 5-year survival rate is approximately 60% for stage I lung cancer but is only 1% for those with stage IV disease. The potential of early detection of lung cancer to improve outcomes has for the first time been shown to benefit from a screening program with CT, NLST, on over 53,000 high risk smokers and ex-smokers showed a 20% mortality benefit for screening with CT compared to chest X-ray. This confirmed previous screening study reports which showed an increase in early stage and longer survival in populations which had been screened for lung cancer ([2-4]). Lung cancer five-year survival rates in the US have remained at approximately 16% for decades. However, CT screening is expensive and initial calculations from the trial show it will be difficult to achieve a cost-effective position to justify broad screening use. Another concern with CT is the large

number of false positive results which are produced. It is therefore very important to find a test that can further enhance the performance of CT.

About *Early*CDT–Lung

*Early*CDT–Lung – is a simple blood test that detects cancer at its earliest stages of development. *Early*CDT–Lung has been available in the US for more than two years and has been shown to detect early and late stage cancers in research studies as well as in clinical use. An audit of more than 1,600 patients, confirms the test performs in the clinical setting as expected. Oncimmune's *Early*CDT-Lung test uses a panel of tumor antigens to detect the presence of immuno-biomarkers (autoantibodies) produced by the patient's immune system when lung cancer is present. Elevation of any one of the panel of immuno-biomarkers (autoantibodies) above a predetermined cut-off value suggests that a tumor might be present. Previous studies have shown that immuno-biomarkers, in some cases, can be detected up to five years earlier than tumors can be seen in routine diagnostic imaging procedures. Tests that detect autoantibodies to a single tumor protein have been available for a number of years but have had low pick up rates (sensitivity). Previously, multiple antigen tests had low specificity, especially for early detection. Oncimmune's *Early*CDT-Lung test has increased the sensitivity of the autoantibody test while maintaining a high level of specificity. The test is performed in Oncimmune's CLIA-certified laboratory in metro Kansas City.

About CEAC

Based on the early work of Professor Robertson, CEAC is leading research into the early detection and management of cancer and pushing forward the introduction of a blood test which can pick up the first signs of cancer as much as five years before some patients present with symptoms. Officially opened in January this year CEAC brings together a multi-disciplinary team of experts to lead to a better understanding of the molecular pathways that cancers in humans exploit as they develop and spread. This will help cancer specialists gain a greater insight into the associated immune response. The Centre is based at The University of Nottingham's School of Graduate Entry Medicine and Health in Derby, England. Cancer: Early Detection is a flagship project within the University's new appeal, Impact: The Nottingham campaign, which aims to raise £150m to change lives, tackle global issues and shape the future.

About Oncimmune

Oncimmune Ltd was founded in 2003 as a spin out company from the University of Nottingham and is an industry leader in early cancer detection. The company is committed to advancing early cancer detection through proprietary immuno-biomarker technologies 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% of solid-tumor cancers, which make up 70% of all cancers including lung, breast, colorectal, prostate, stomach, pancreatic and ovarian. Oncimmune (USA) LLC, founded in 2006, is the North American headquarters for Oncimmune and all testing is performed exclusively at Oncimmune's CLIA- regulated laboratory located in the Kansas City area. Oncimmune (USA) LLC is a wholly owned subsidiary of Oncimmune Ltd. Oncimmune Ltd owns a portfolio of patents, including Patent Nos. 7,402,403 and 7,205,117, with five others currently filed and under review. For further information visit www.earlycdt-lung.com, www.oncimmune.com or www.hellohaveyouheard.com

About National Jewish Health

National Jewish Health is known worldwide for treatment of patients with respiratory, cardiac, immune and related disorders, and for groundbreaking medical research. Founded in 1899 as a nonprofit hospital, National Jewish Health remains the only facility in the world dedicated exclusively to these disorders. Since 1998, *U.S. News & World Report* has ranked National Jewish the #1 respiratory hospital in the nation.

Safe Harbor Statement

Except for historical information contained herein, statements made in this release that would constitute forward-looking statements may involve certain risks and uncertainties. All forward-looking statements made in this release are based on currently available information and the company assumes no responsibility to update any such forward looking statements.

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