



Major Lung Cancer Screening Trial announced by the NHS in Scotland Using an Innovative Blood Test, EarlyCDT(R) -- Lung

Efforts to enable the early detection of lung cancer when treatment options are most successful to begin fourth quarter 2012

DESOTO, Kan., March 22, 2012 /PRNewswire/ --

Introduction

Sir Harry Burns, The Chief Medical Officer for Scotland announced today that Scotland will conduct a major screening trial for lung cancer using *EarlyCDT-Lung* – a simple blood test that detects cancer at its earliest stages of development. *EarlyCDT-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 1,500 patients has been overseen by independent leading cancer clinicians and confirms the test performs in the clinical setting as expected. The objective of this randomized prospective trial is to ascertain the cost-effectiveness of *EarlyCDT-Lung* in screening high risk patients. Initial calculations from an independent firm of health economists in Boston show that it should be highly cost effective and reduce lung cancer mortality. Lung cancer five-year survival rates in the US have remained at approximately 16% for decades.

The trial will include 10,000 high-risk smokers (defined as having smoked the equivalent of 20 cigarettes per day for over 20 years). Half of the identified population will have *EarlyCDT-Lung*; those who are positive will be followed up with low dose computed tomography (CT) scans in order to identify if lung cancer is present. The other half will not be screened with *EarlyCDT-Lung* but will have the current standard of care.

The clinical outcomes and the overall cost of care, including using the *EarlyCDT-Lung* test, will be compared with the clinical outcomes and the overall cost of care of the non-screened group.

Why Conduct this Trial Now?

The outlook for lung cancer has for the first time been shown to benefit from a screening program with CT. The National Lung Screening Trial (NLST)(1) on over 53,000 high risk smokers and ex-smokers showed a 20% mortality benefit for screening with CT compared to chest X-ray. 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. The UK has an additional issue to contend with, as do many countries across the globe, which is an insufficient number of CT scanners to support a national screening program. 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 is a pre-screen for CT that reduces the overall cost to an acceptable level and thus will allow the mortality benefit of screening with CT to become a practical reality. *EarlyCDT-Lung* will detect approximately half the cancers in the screened population and reduce the overall number to be followed up with CT to 7%. Having up to half the cancers in only 7% of the screened population should make the combination of *EarlyCDT-Lung* followed by CT highly cost effective. Initial calculations show that it may even reduce the overall cost of care for the Scottish high risk population while at the same time saving a significant number of lives.

Sir Harry Burns stated:

"The earlier a cancer is diagnosed the greater the chance it can be treated successfully, and currently 85 percent of patients with lung cancer remain undiagnosed until the disease has reached an advanced stage. This pilot project is part of our Detect Cancer Early programme, which aims to increase the early detection of cancer by 25 percent. By testing those at greatest risk of developing lung cancer, and diagnosing it at its earliest possible stage, we stand a better chance of being able to treat the cancer successfully. This means patients can be treated when their general health is better and when less aggressive treatment may be required than if the cancer had spread."

Professor John Robertson (Director of CEAC, and Founder and Chief Scientific Officer of Oncimmune Ltd) said:

"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. The significant amount of performance validation work that we carried out before the test was launched in the US has led to the test performing commercially as expected. A randomised screening trial of this nature will help validate its use as a screening tool."

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".

Dr. Frank Detterbeck, Professor and Chief, Thoracic Surgery, Yale University School of Medicine, commented:

"This is a really important study. We know now that screening with CT imaging can save a lot of lives by early detection of lung cancer, but broad implementation of CT screening is not so easy. The significance of this blood test is the extensive and careful study, validation and re-validation that has produced consistent robust results, and the ease of use. The launch of this trial is another example of the thoroughness of the scientific data that stands behind this test."

More about *EarlyCDT-Lung*

Oncimmune's *EarlyCDT-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 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 *EarlyCDT-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.

More about the Trial and Lung Cancer

The trial will be conducted in Scotland. It will start before the end of 2012 and the first results are expected to be reported before the end of 2014. The sponsors for the trial are the NHS in Scotland, CEAC (the Centre of Excellence for Autoimmunity in Cancer at the University of Nottingham) and Oncimmune Ltd. The trial is part of Scotland's Detect Cancer Early programme which aims to increase the early detection of cancer by 25 per cent.

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. Moreover, Scotland has had one of the highest rates of lung cancer in the world. Approximately 2,460 men and 2,340 women are diagnosed with lung cancer in Scotland every year, 16% of the UK lung cancer total, despite Scotland having only 8% of the UK's population. (2008 data). 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 was confirmed recently by the National Cancer Institute's National Lung Screening Trial (NLST) which showed a 20% reduction in deaths from lung cancer as a result of early detection of the disease(1). 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).

More 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 pounds Sterling to change lives, tackle global issues and shape the future.

More 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.

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.

For further information visit www.earlycdt-lung.com, www.ancimmune.com or www.hellohaveyouheard.com

References:

- (1) The National Lung Screening Trial Research Team Reduced Lung-Cancer Mortality with Low-Dose Computed Tomographic Screening N Engl J Med 2011;365:395-409.
- (2) Swensen SJ et al. CT screening for lung cancer: five-year prospective experience. Radiology 2005; 235:259265.
- (3) Henschke CI, et al. Early lung cancer action project: overall design and findings from baseline screening. Lancet 1999; 354: 99105.
- (4) Henschke CI et al. Early lung cancer action project: initial findings on repeat scanning. Cancer 2001; 92:153159

SOURCE Oncimmune (USA) LLC

[Back to top](#)

RELATED LINKS

<http://www.ancimmune.com>

Find this article at:

<http://www.prnewswire.com/news-releases/major-lung-cancer-screening-trial-announced-by-the-nhs-in-scotland-using-an-innovative-blood-test-earlycdt----lung-143789146.html>

Check the box to include the list of links referenced in the article.

