

PRESS RELEASE

4th SEPTEMBER 2015

**Encouraging early results of major 10,000 patient
NHS Lung Cancer Screening Trial using *EarlyCDT*®-Lung test
to be announced at the
16th World Conference on Lung Cancer**

- *Encouraging early results – cancer pick up rate considerably better than stated test performance; positivity rate as expected*
- *The study is the **largest randomised trial for the early detection of lung cancer using biomarkers** ever conducted*
- *Final results may enable the adoption of **EarlyCDT-Lung** screening by **other countries***

Nottingham, UK - 4th September 2015: Encouraging early results from the largest ever randomised trial for lung cancer using autoantibody biomarkers are being released on 7th September at the International Association for the Study of Lung Cancer's 16th World Conference on Lung Cancer. The initial results of the National Health Service (NHS) Scotland[†] ECLS study of 10,000 high-risk smokers are being presented by Professor Frank Sullivan FRSE, FRCP, FRCGP, CCFP Abstract #48: *"Progress with a randomised controlled trial of the detection in blood of autoantibodies to tumour antigens as a case-finding method in lung cancer using the **EarlyCDT-Lung** test in Scotland (ECLS)."*

The ECLS Study uses the **EarlyCDT-Lung** blood test developed by Oncimmune, a leader in early cancer detection. The early results of the Study demonstrate the cancer detection rate (sensitivity) of 81% which is considerably better than the test performance states at 41%. The positivity rate is as expected with a specificity of 91%. However it should be noted that the control arm has not been formally assessed. The final data on the control arm will be collected at the end of the study.

Professor Frank Sullivan, Chief Investigator of the ECLS Study said: *"ECLS has recruited almost 10 000 patients so far and will complete recruitment of 12 000 in early 2016 with full results available after two years of follow up. It has been a major effort to recruit such an impressive number of study subjects so far. Overall positivity rate for the test is as expected at 91%. Provisional encouraging data reporting the numbers of early cancers being detected in the test arm is being presented at the World Conference on Lung Cancer (WCLC) in Denver on 7th September."*

First announced in March 2012, the ECLS Study is designed to determine whether use of the **EarlyCDT-Lung** test leads to earlier detection of lung cancer and can help to save lives in the long term. The rationale is that patients pre-identified as being at high risk of lung cancer take the **EarlyCDT-Lung** test. Those who receive a positive

result are effectively triaged into a much higher risk group and are referred for X-ray and Low Dose Computed Tomography (LDCT). This high-risk selection protocol results in many fewer LDCTs but with the same, already established National Lung Screening Trial (NLST) mortality benefit of LDCT.

These are initial results only - further interim results will be announced over the next three years with final publication expected in 2018-2019. These study results will enable the NHS to make a decision about whether to offer the **EarlyCDT-Lung** test as a nationwide screening test in the future and may enable the adoption of **EarlyCDT-Lung** screening by **other countries**. Almost 10,000 high-risk patients have already been enrolled into the study, however recruitment will continue until it reaches 12,000, in order to ensure a robust statistically 'powered' result is achieved - one that is statistically significant in as short a period of time as possible.

Geoffrey Hamilton-Fairley, CEO of Oncimmune Limited said: *"We are pleased by the initial results of this independent study which bears out the wealth of data on the use of autoantibodies in cancer detection and are consistent with our previous EarlyCDT-Lung validation studies. If these results continue, it will further underpin the rationale of the ECLS study – namely that screening with EarlyCDT-Lung can be effective for the early detection of lung cancer, helping to save lives and money. We look forward to ECLS reporting updates on an ongoing basis."*

About EarlyCDT-Lung

EarlyCDT[®]-Lung is a simple blood test which is ordered by a doctor to aid in the risk assessment and early detection of lung cancer in moderate and high risk patients and to stratify indeterminate pulmonary nodules for the risk of malignancy. The test's overall accuracy is greater than 91%[‡].

When a tumour is present it produces abnormal proteins (known as antigens). Antigens from a person's own cells are not normally found in the body. The body reacts to these antigens by producing autoantibodies. The test measures a panel of seven autoantibodies to detect the presence of lung cancer.

EarlyCDT-Lung has been developed so that individuals at moderate or high risk of developing lung cancer can benefit from an increasing chance that lung cancer can be detected at the earliest possible stages, when treatment can be most successful. The **EarlyCDT-Lung** test can also be used in conjunction with diagnostic imaging such as X-ray or CT scan to further assess the risk of lung cancer being present where indeterminate lung nodules have been detected which may or may not be a sign of cancer.

About Oncimmune

Oncimmune is an industry leader in early cancer detection. The company has pioneered the development of autoantibody assay technologies that have the potential to allow earlier cancer detection than other methods and be applied to a very wide range of solid tumour types. The Company's proprietary **EarlyCDT[®]** technology platform was launched in 2009 and **EarlyCDT[®]-Lung** is available through

physicians in the US and also privately in the UK and other regions. *EarlyCDT*[®] tests for liver and ovarian cancer are in final validation.

Oncimmune is headquartered in Nottingham, United Kingdom with testing facilities in the US.

For more information: www.oncimmune.com

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About the ECLS Study

Lung cancer kills more people than any other cancer worldwide, with over 1.5 million deaths globally in 2012. In Scotland, nearly 5,000 people die from lung cancer every year.[§]

It is often hard to find lung cancer early. Most people with early lung cancer do not have any symptoms, so only a small number of lung cancers are found at an early stage when treatment can be most successful. It is for this reason that the Scottish Government is co-funding the Early Cancer Detection test – Lung cancer Scotland (ECLS) Study along with Oncimmune Ltd, the company which developed *EarlyCDT-Lung* - the test being trialed in the study. This blood test, *EarlyCDT-Lung*, may be able to pick up very small lung cancers before they cause health problems.

The Study originally invited 10,000 high-risk people from Tayside, Glasgow and the surrounding areas to participate. It is planned that an extra 2,000 patients will now be recruited and some of these will come from Lanarkshire. These regions have been chosen because lung cancer is more common in these areas. Those who agree to take part in the Study either receive an *EarlyCDT-Lung* test or are followed up by usual care. Participants with a positive test are offered a chest X-ray and a series of CT scans over two years. All participants requiring further investigations or treatment are treated within NHS guidelines. For more information:

<http://www.eclsstudy.org/home>

A key outcome of this study will be the cost-effectiveness of screening high-risk patients with **EarlyCDT-Lung**. Although the first statistically powered results will be published in 2018 or 2019 the ECLS study wants to find out if earlier detection saves lives in the long term by following everyone who takes part in the study for up to 10 years. The Study will also seek patients' feedback about the test so that this can be included as part of the decision about whether to offer it as a nationwide lung cancer-screening test.

[†] ECLS Study is co-sponsored by NHS Tayside and University of Dundee

[‡] Source: *EarlyCDT[®]-Lung test: improved clinical utility through additional autoantibody assays.* Chapman CJ, Healey GF, Murray A, Boyle P, Robertson C, Peek LJ, Allen J, Thorpe AJ, Hamilton-Fairley G, Parsy-Kowalska CB, Macdonald IK, Robertson JFR. *Tumor Biol.* 201;33(5):1319-26. doi: 10.1007/s13277-012-0379-2

[§] Sources: Cancer Research UK (<http://www.cancerresearchuk.org/health-professional/cancer-statistics/statistics-by-cancer-type/lung-cancer/incidence>). American Cancer Society (<http://www.cancer.org/cancer/lungcancer-non-smallcell/detailedguide/non-small-cell-lung-cancer-key-statistics>).