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Oncimmune Holdings plc
("Oncimmune" or the "Company")

Ground-breaking trial demonstrates potential of blood test which harnesses the power of the immune system to reduce late detection of lung cancer

- **Positive results for Early detection of Cancer of the Lung Scotland ("ECLS") trial presented at the World Conference for Lung Cancer in Barcelona**

- **The ECLS trial, conducted in Scotland with 12,209 patients, is believed to be the largest randomised controlled trial using blood biomarkers for the detection of lung cancer**

- **Further validates the use of Oncimmune's platform technology as a screening modality, which can detect cancer four years or more before standard clinical diagnosis**

Oncimmune Holdings plc (AIM: ONC.L), a leading global immunodiagnostics group, welcomes the presentation of data today by Professor Frank Sullivan (Chief Investigator on the ECLS trial) which has demonstrated the potential of Oncimmune's EarlyCDT Lung test to reduce the incidence of patients with late-stage lung cancer at diagnosis, compared with standard clinical diagnosis.

In a randomised controlled trial of 12,209 people in Scotland at high risk of developing lung cancer, it was shown that more people were diagnosed at an early stage of the disease in the two years after taking the EarlyCDT Lung test than those in the control arm who received standard clinical care.

The findings, presented at the 2019 World Conference on Lung Cancer hosted by the International Association for the Study of Lung Cancer (IASLC) in Barcelona today, are an important validation of Oncimmune's diagnostic platform technology which harnesses the power of the immune system, to detect evidence of the body's natural response to cancer. The technology can detect cancer four years or more before standard clinical diagnosis.

Oncimmune's patented technology works by detecting the presence of autoantibodies generated by the body's immune system as a natural defence against cancer cells. Lung cancer was chosen as the first target of the technology because it is the world's leading cause of cancer-related death and is often detected at an advanced stage with approximately 85% of patients in the UK undiagnosed until the disease has spread to other parts of the body.[1]

The ECLS trial is believed to be the largest randomised controlled trial for the detection of lung cancer using biomarkers conducted anywhere in the world.

Among those people who received the EarlyCDT Lung test and went on to develop lung cancer within the next two years, 41.1% were diagnosed at an early stage (stage 1&2) of the disease, compared with 26.8% among the control group subject to standard clinical practice. This resulted in a 36% reduction in late stage presentation after 2 years of follow up in subjects randomised to the EarlyCDT test.

The trial also showed a lower rate of deaths among people in the intervention arm of the trial after two years compared with people in the control group. Lung cancer-specific deaths were also lower in the intervention group. This suggests that the EarlyCDT Lung test followed by CT imaging could produce a mortality benefit, although the trial was not powered to demonstrate such a trend after two years.

The next step is to move to a larger population-based evaluation in up to 200,000 patients to assess the implications of diagnosis with EarlyCDT Lung on survival and mortality in a real-world setting.

Adam Hill, Chief Executive Officer of Oncimmune, commented: *"We are thrilled that the ECLS trial has demonstrated so clearly the potential of our EarlyCDT technology platform to transform the way cancer is diagnosed. We look forward to working with health authorities in Scotland and beyond to roll out EarlyCDT Lung more widely, with the aim of saving lives and reducing costs for the NHS and other healthcare systems around the world. Meanwhile, we are continuing to test our technology on other forms of cancer, including liver, ovarian, breast and prostate, in pursuit of our ambition to build the leading immunodiagnostic platform in the field of oncology."*

Professor Frank Sullivan, Professor of Primary Care Medicine at the University of St. Andrews, **the Chief Investigator for the ECLS trial, commented**: *"These landmark findings are likely to have globally significant implications for the early detection of lung cancer by showing how a simple blood test, followed by CT scans, is able to increase the number of patients diagnosed at an earlier stage of the disease, when surgery is still possible and prospects for survival much higher."*

Details of the ECLS trial

Today's Presidential Symposium presentation at the IASLC World Conference on Lung Cancer builds on positive top line results announced in June and confirms that the ECLS trial met its primary endpoint.

The trial was open to adults aged 50–75 considered to be at high risk of lung cancer because of smoking and family history, and healthy enough to undergo potentially curative therapy. The intervention was the EarlyCDT Lung test, followed by X-ray and computerised tomography (CT) scan in those with a positive test result. The comparator was standard clinical practice in the UK. The primary endpoint was the difference, at 24 months after randomisation, between the rates of patients with stage III, IV or unclassified lung cancer at diagnosis in the intervention arm and those in the control arm. There are also a number of secondary endpoints, details of which will be provided when the trial is fully reported.

The trial was sponsored by the University of Dundee and NHS Tayside and co-funded by the Scottish Chief Scientist Office, Scottish Government and Oncimmune. It was headed by Chief Investigators Professor Frank Sullivan, Professor of Primary Care Medicine at the University of St. Andrews, and Dr Stuart Schembri, until recently consultant Physician in Respiratory and General Internal Medicine at NHS Tayside.

The oral presentation was made by Professor Sullivan in the Presidential Symposium of the World Conference for Lung Cancer 2019, the world's largest meeting dedicated to lung cancer and other thoracic malignancies, hosting more than 7,000 delegates from more than 100 countries. A submission on the full ECLS trial is currently being prepared for a leading peer-reviewed medical publication.

Background

Lung cancer is the most common cause of death from cancer in Scotland. A quarter of all deaths from cancer in Scotland are attributed to lung cancer. The number of deaths due to lung cancer is more than double that of colorectal cancer, the next most common cause of death from cancer. 5,331 new cases of lung cancer were diagnosed in 2017 (2,592 males and 2,739 females) with 4,069 deaths from the disease recorded that same year.[2]

In the UK, survival from lung cancer is poor with less than 9% of patients still alive at five years after diagnosis, due primarily to the late stage of presentation. Early detection and diagnosis of cancer improves prognosis; the current five-year survival rate is approximately 60% for stage I lung cancer but is only 1% for those with stage IV disease.[1]

The US National Cancer Institute National Lung Screening Trial (NLST) reported that CT screening reduced lung cancer mortality by 20%. This has led to a number of guidelines in the United States which advocate lung cancer screening with low dose CT. More recently the UK Lung Cancer Screening Trial and the NELSON trial reported successful early detection of lung cancer using low dose CT scans. However, as a primary screening modality CT is expensive and leads to a significant percentage of false positives (>90% of lung nodules are found to be benign). There was a substantial increase in morbidity associated with further investigation.

The EarlyCDT Lung test is a novel autoantibody diagnostic test for the early detection of lung cancer allowing stratification of individuals according to their risk of developing lung cancer. This could permit a targeted approach to CT scanning for early lung cancer detection which may be a more cost-effective and potentially less harmful approach to population screening.

1. Early Detection of Cancer of the Lung Scotland (ECLS): Trial results. (2019). IASLC 2019 World Conference on Lung Cancer. Abstract available from 10:15 CEST, 09 Sep 2019 https://bit.ly/2ky8Glo
2. Isdscotland.org. (2019). *Cancer | Cancer Statistics | Lung Cancer and Mesothelioma | Health Topics | ISD Scotland*. [online] Available at: https://www.isdscotland.org/Health-Topics/Cancer/Cancer-Statistics/Lung-Cancer-and-Mesothelioma/ [Accessed 6 Sep. 2019].

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About Oncimmune

Beating cancer, one test at a time

The battle against cancer hinges on early detection and then the delivery of effective treatment. Oncimmune is working to revolutionise both the detection of cancer and its treatment by harnessing the sophisticated disease detecting capabilities of the immune system to find cancer in its early stages. Our range of diagnostic tests assist clinicians to identify the presence of cancer four years or more before standard clinical diagnosis, whilst our technology platform and sample biobanks are helping healthcare companies to develop new cancer treatments.

Oncimmune was founded in 2002 and launched its platform technology in 2009, followed by its first commercial tests, EarlyCDT Lung and EarlyCDT® Liver. To date, over 158,000 tests have been performed for patients worldwide. EarlyCDT Lung was also used in what is believed to be the largest randomised controlled trial for the early detection of lung cancer using biomarkers, the successful National Health Service (NHS) ECLS trial of 12,209 high-risk smokers in Scotland which demonstrated EarlyCDT Lung reduced the incidence of patients with late-stage lung cancer or unclassified presentation at diagnosis, compared to standard clinical practice.

Oncimmune, headquartered at its laboratory facility in Nottingham, UK, has a discovery research centre in Dortmund, Germany and a CLIA lab in Kansas, US as well as an office in London, UK and a partner representative office in Shanghai, China. Oncimmune joined the Alternative Investment Market (AIM) of the London Stock Exchange in May 2016 under the ticker ONC.L.

Oncimmune®

What is EarlyCDT Lung?

A blood test using a panel of seven immunogenic proteins for the testing of tumour-related antibodies specific to lung cancer.

For more information, visit www.oncimmune.com