



## **Oncimmune Demonstrates Clinical Utility of Early Lung Cancer Detection Test at IASLC World Conference on Lung Cancer**

### ***Use of EarlyCDT<sup>®</sup>-Lung results in a high positive predictive value for detecting malignancy in indeterminate pulmonary nodules, with a low resection rate for benign disease***

**De Soto, Kansas, September 25, 2018** – Oncimmune Holdings plc (AIM: ONC.L), a leading early cancer detection company developing and commercializing its proprietary *EarlyCDT<sup>®</sup>* liquid biopsy platform technology, today presented new data demonstrating the clinical utility of *EarlyCDT-Lung*, a simple blood test for the early detection of lung cancer, in determining malignancy risk in indeterminate pulmonary nodules (IPNs). In a presentation today at the IASLC 19<sup>th</sup> World Conference on Lung Cancer in Toronto, Canada, hosted by the International Association for the Study of Lung Cancer (#WCLC2018), Oncimmune researchers reported that for IPNs of 6-20mm with a lung cancer probability of >30%, combining a positive *EarlyCDT-Lung* result with a standard risk calculator produced a positive predictive value (PPV) of 91%, versus a 48% PPV using the standard risk calculator alone. Additionally, use of *EarlyCDT-Lung* led to a resection rate for benign disease of only 9%, compared with the average of 20-25% reported in previously published lung cancer screening trials.

*EarlyCDT-Lung* assesses malignancy risk in IPNs, which are radiographic opacities in the lung that carry some risk of cancer. Nearly 1.6 million Americans have an incidentally detected nodule on the lung each year, due to the increase in computed tomography (CT) scanning. The majority of these IPNs are of intermediate risk (10%-65%). *EarlyCDT-Lung*, which is indicated for use in intermediate-risk nodules, helps find IPNs that are cancerous.

“These data confirm the high specificity of the *EarlyCDT-Lung* blood test, which can potentially detect lung cancer four years or more, on average, before diagnosis via standard care pathways,”<sup>1,2</sup> said Oncimmune U.S. Chief Medical Officer James Jett, MD. “A positive test result provides new, independent data to inform clinicians’ decision-making, allowing them to ‘rule-in’ lung cancer and intervene earlier, while also leading to a lower resection rate for benign disease.”

The presentation at IASLC builds on study results published in the *Journal of Thoracic Oncology* in 2017, in which the addition of *EarlyCDT-Lung* to standard risk models improved diagnostic performance with high specificity (>92%) and a high PPV (>70%).<sup>3</sup> The latest analysis is derived from 1,987 individuals in the U.S. who had an *EarlyCDT-Lung* blood test performed because their physician considered them at high risk for lung cancer. Forty-eight of those patients had an IPN of 6-20mm and a calculated risk of malignancy exceeding 30%, based on the Swensen/Mayo calculator, a commonly used model to estimate lung cancer risk. Of those 48 patients, 25 had benign nodules and 23 had nodules that were identified as lung cancer. The PPV was 48% (23/48) based on the nodule calculator alone. With a positive *EarlyCDT-Lung* result and a calculated risk

of >30%, the PPV was 91% (10/11). The investigators characterized the 9% resection rate for benign disease as a marked improvement over that reported in lung cancer screening trials.

“There is a definitive body of evidence supporting the clinical utility of *EarlyCDT-Lung*,” noted Adam M. Hill, MB, PhD, global chief medical officer and chief strategy officer at Oncimmune. “That evidence, along with the high prevalence of intermediate-risk IPNs, suggests that *EarlyCDT-Lung* is a valuable tool in early lung cancer detection, and will help us expand our business in the U.S. and other markets.”

### **About *EarlyCDT*<sup>®</sup>-Lung**

*EarlyCDT-Lung* is a simple, affordable blood test for the early detection of lung cancer. The extensively validated test measures blood levels of seven autoantibodies to tumor-associated antigens that are linked to lung cancer. Unlike the antigens themselves, the autoantibody levels can be measured easily and accurately, due to the signal magnification created by the body’s immune response to cancer. *EarlyCDT-Lung* is highly specific in detecting all types of lung cancer at all stages of disease (I-IV), making the test complementary to the high sensitivity but poor specificity (i.e., high rate of false-positive results) of CT scanning.

### **About Oncimmune<sup>®</sup>**

Oncimmune is a leading early cancer detection company developing and commercialising its proprietary *EarlyCDT*<sup>®</sup> platform technology. Oncimmune has pioneered the development of autoantibody tests that can detect cancer four years or more before diagnosis and can be applied to a wide range of solid tumor types. The Company's first product, *EarlyCDT-Lung*, was launched in 2012, as a CLIA test in the U.S., and since then over 156,000 commercial tests have been sold. *EarlyCDT-Lung* is available through physicians in the U.S. and also privately in the United Kingdom (UK), Europe, and Asia. *EarlyCDT-Lung* is being used in the National Health Service (NHS) Scotland ECLS study of 12,210 high-risk smokers, the largest-ever randomised trial for the early detection of lung cancer using biomarkers. *EarlyCDT*<sup>®</sup>-Liver launched in May 2018 and further tests are in development.

Oncimmune, headquartered in Nottingham, UK with operations and testing facilities in De Soto, Kansas, joined the London Stock Exchange (AIM) in May 2016 under the ticker **ONC.L**. For more information, visit [www.oncimmune.com](http://www.oncimmune.com)

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<sup>1</sup>Zhong L, et al. Profiling tumour-associated antibodies for early detection of non-small cell lung cancer. *J Thorac Oncol* 2006; 1:513-519.

<sup>2</sup>Jett J, et al. Determination of the detection lead time for autoantibody biomarkers in early stage lung cancer using the UKTOCS cohort. *J Thorac Oncol* 2017; 12(11):S2170.

<sup>3</sup>Massion PP, et al. Autoantibody signature enhances the positive predictive power of computed tomography and nodule-based risk models for detection of lung cancer. *J Thorac Oncol*. 2017;12(3):578-84. doi:10.1016/j.jtho.2016.08.143.

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