

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

**Oncimmune Publishes Study Showing Cost-Effectiveness of *EarlyCDT*<sup>®</sup>-Lung Test in Early Detection of Lung Cancer in Patients with Indeterminate Pulmonary Nodules**

**Nottingham, UK – 23 May 2018:** Oncimmune Holdings plc (AIM: ONC.L), a leading early cancer detection company developing and commercialising its proprietary *EarlyCDT*<sup>®</sup> liquid biopsy platform technology, today announces the publication of results showing the cost effectiveness of its blood-based autoantibody test, *EarlyCDT*<sup>®</sup>-Lung, versus computed tomography (CT) surveillance alone, in the evaluation of incidentally-detected pulmonary nodules. The study was jointly conducted by the health economics consultancy Policy Analysis Inc. and published in PLOS ONE.

Patients who have incidentally detected pulmonary nodules and an estimated intermediate risk (5%-65%) of lung cancer are frequently accessed via CT surveillance to detect nodule growth, despite ACCP guidelines for a more aggressive diagnostic strategy such as positron emission tomography-computed tomography (PET-CT). This study examined whether initial administration of the *EarlyCDT*<sup>®</sup>-Lung test to intermediate-risk patients, in lieu of CT surveillance alone, could improve outcomes by earlier intervention and thus earlier diagnosis of lung cancer in a cost-effective manner.

The study results indicated that the use of *EarlyCDT*<sup>®</sup>-Lung is likely to be a cost-effective use of healthcare resources as it results in earlier diagnosis of lung cancer in patients with incidentally detected pulmonary nodules, who are estimated to be at intermediate risk of lung cancer and who are scheduled for CT surveillance alone. The standard QALY (cost for every Quality Adjusted Life Year) accepted as cost effective by payors is \$50,000 or less and this publication shows that *EarlyCDT*<sup>®</sup>-Lung has a QALY of half this at \$25,000.

The Company believes this publication, in addition to the many already published papers validating performance of the *EarlyCDT*<sup>®</sup>-Lung test<sup>i, ii, iii</sup> and its clinical performance in the field published by the Journal of Thoracic Oncology<sup>iv, v</sup>, makes a compelling case to both clinicians and payors that the use of *EarlyCDT*<sup>®</sup>-Lung leads to a cost-effective improvement in outcomes.

**Dr Jim Jett, Chief Medical Officer (US) of Oncimmune, said:** "The evaluation of incidentally discovered pulmonary nodules is an increasingly common problem for clinicians. Published guidelines recommend PET-CT for evaluation of intermediate risk nodules but often these guidelines are not followed in favour of CT surveillance alone. These results show that the use of *EarlyCDT*-Lung, our simple, blood-based autoantibody test which can detect cancer four years earlier than other methods, could be cost effective when used to improve diagnosis and patient outcomes."

**Geoffrey Hamilton-Fairley, Chief Executive Officer of Oncimmune, commented:** "Oncimmune has always acknowledged that the health economics around its tests will be key to their uptake as they roll out commercially. We have spent many years working with Policy Analysis (PAI) to develop models, using independent inputs, for our tests and we have used these estimates before embarking on product development to make sure the ultimate results will have both clinical validity and be cost effective. This publication demonstrates that our approach is sound and we will now move forward with a complete set of relevant publications relating to the use of *EarlyCDT*<sup>®</sup>-Lung in the risk evaluation of intermediate pulmonary nodules, to help us accelerate adoption in the US."



The full manuscript entitled: Cost-Effectiveness of an Autoantibody Test (*EarlyCDT<sup>®</sup>-Lung*) as an Aid to Early Diagnosis of Lung Cancer in Patients with Incidentally Detected Pulmonary Nodules is available online at <http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0197826>

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**About Oncimmune**

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 up to four years earlier than other methods and can be applied to a very wide range of solid tumour types. The Company's first product, *EarlyCDT<sup>®</sup>-Lung*, was launched in 2012, as a CLIA test in the USA and since then over 155,000 commercial tests have been sold. *EarlyCDT<sup>®</sup>-Lung* is available through physicians in the US and also privately in the UK and other regions. *EarlyCDT<sup>®</sup>-Lung* is being used in the largest ever randomised trial for the early detection of lung cancer using biomarkers, the National Health Service (NHS) Scotland ECLS study of 12,210 high-risk smokers. The Company's second product, *EarlyCDT<sup>®</sup>-Liver*, was launched in May 2018 as a CLIA test in the US.

Oncimmune, headquartered in Nottingham, United Kingdom with testing facilities in the US, joined 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>i</sup> Jett JR, Peek LJ, Fredericks L, et al. Audit of the Autoantibody Test, *EarlyCDT<sup>®</sup>-Lung*, in 1600 Patients: An Evaluation of its Performance in Routine Clinical Practice. *Lung Cancer*. 2014; 83:51-55
- <sup>ii</sup> Zhong L, et al. Profiling Tumour-Associated Antibodies for detection of Non-Small Cell Lung Cancer. *J Thor Oncol* 2006; 1:513-519.
- <sup>iii</sup> Jett J, et al. Determination of the detection lead time for autoantibody biomarkers in early stage lung cancer using the UKCTOCS cohort. *J Thor Oncol* 2017; 12(11): S2170
- <sup>iv</sup> Massion PP, Healey GF, Peek LJ, Fredericks L, Sewell HF, Murray A, Robertson JF. Autoantibody Signature Enhances the Positive Predictive Power of Computed Tomography and Nodule-Based Risk Models for Detection of Lung Cancer. *J Thorac Oncol* 2017 Mar;12(3):578-584. doi: 10.1016/j.jtho.2016.08.143. Epub 2016 Sep 8
- <sup>v</sup> Healey GF, Macdonald IK, Reynolds C, Allen J, Murray A. Tumor-Associated Autoantibodies: Re-Optimization of EarlyCDT-Lung Diagnostic Performance and Its Application to Indeterminate Pulmonary Nodules. *J Cancer Therapy* 2017; 8:506-517. doi: 10.4236/jct.2017.85043