LUNG CANCER BLOOD TEST

Early Detection of Lung Cancer: The Number 1 Cancer Killer

Cancer is curable if it is caught early, before there is metastasis. Many organizations are working on developing methods to detect cancer before a patient experiences symptoms or there is clinical evidence of disease, and research in this arena is yielding everything from electronic noses that can sniff out cancer to sputum and blood tests that assess for certain biomarkers. *Oncology Net Guide* had the opportunity to speak with William Jewell, MD, a renowned surgical oncologist, and medical director of Oncimmune (www.oncimmune.com), a company that is committed to advancing early cancer detection.

The tests developed by Oncimmune use proprietary autoantibody assay technologies based on biological technology identified by John Robertson, MD, professor of surgery, Nottingham University, England, and chief scientific officer of Oncimmune, which is based in Kansas. The company's mission is to develop screening tests to identify more than 90% of solid-tumor cancers, including lung, breast, colorectal, prostate, stomach, pancreatic, and ovarian. We asked Dr Jewell about the *Early*CDT-Lung test, which became available this August.

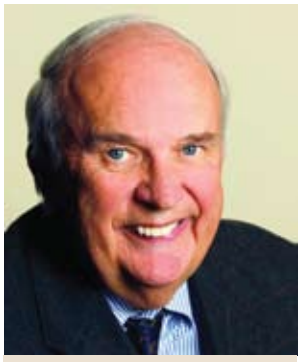
ONG: What are the benefits of the *Early*CDT-Lung test compared with traditional testing, and how much earlier is it able to detect cancer?

Dr Jewell: *Early*CDT-Lung™ is a simple blood test that requires approximately a 5-mL blood sample to be taken from the patient. A blood draw requires much less time and is much simpler to perform than diagnostic imaging, bronchoscopy, or a sputum sample analysis. The test has the ability to detect cancer developing in the earliest stages of the disease. Data from laboratory studies conducted by Dr John Robertson, Oncimmune's chief science officer, who developed *Early*CDT-Lung, as well as studies conducted by numerous academic researchers, confirm that autoantibodies formed from some cancers can be measured up to 4 years before there is clinical evidence of disease.

Physicians who use the test say it can detect cancer 3 to 5 years sooner than finding symptoms from a patient. Early detection in asymptomatic, high-risk patient populations is the primary benefit of *Early*CDT-Lung. Currently, the test is being administered at 25 participating physician sites in 11 states and is available at www.oncimmune.com or by calling (888) 583-9030.

ONG: What steps has Oncimmune taken to prepare this test?

Dr Jewell: Developed over the past 5 years, *Early*CDT-Lung is based on the laboratory observations of Dr Robertson, as well as many studies by researchers in other well-known institutions around the world. More than 80,000 subject samples from individuals, both with lung cancer and without, have been tested, resulting in over 8 million individual results. In addition, $25 million has been devoted to the research and development phase of this test. Many academic centers—Scripps Institute, National Cancer Institute, Fred Hutchison Cancer Centre Seattle, Mayo Clinic, and the University of Michigan—have published results on the use of autoantibodies that are consistent with our findings.



William Jewell, MD
Surgical Oncologist

ONG: One of the problems with diagnosing lung cancer early is that, particularly for nonsmokers, early symptoms of lung cancer are often attributed to other conditions, like chronic bronchitis. How do you envision this test being used?

Dr Jewell: The test is generally recommended for individuals who are at high risk for lung cancer or have one or more risk factors associated with lung cancer. Risk factors include a long term history of tobacco smoking; prolonged exposure to specific chemicals and asbestos; scarring of the lungs due to tuberculosis; and recurring pneumonia, bronchitis, or both, to name a few. Some of Oncimmune's participating physicians who are offering *Early*CDT-Lung are also using the test as a follow-up to a computed tomography (CT) scan of a high-risk patient with indeterminate nodules; however, the test can be ordered by a participating physician whenever he or she feels that it is indicated to aid in the diagnosis of lung cancer, which could include any of the aforementioned risk factors.

ONG: What are its rates of sensitivity and specificity?

Dr Jewell: The sensitivity is currently 40% and the specificity is 90%. The positive predictive value is approximately 1:10 (10%).

ONG: What follow-up is required for a negative test result? Would biopsy be the next step for confirming a positive result?

Dr Jewell: A negative test result means that the test did not detect autoantibodies that are associated with a specific tumor. A negative result is not a conclusion that cancer is not present. We recommend that a patient with a negative result continue with regularly scheduled cancer tests as advised by their personal physician. A positive test result indicates that autoantibodies to one or more of the cancer antigens in the test panel exist in quantities exceeding the designated cutoff value. This suggests that a tumor may be present. Oncimmune recommends that the physician combine this information with the results of other tests as an aid in evaluating whether cancer is present. A careful search using CT or magnetic resonance imaging (MRI) scanning would be of value. If a lung lesion is anatomically defined, then at the discretion of the treating physician, further evaluation by biopsy or removal would be reasonable. If the CT or MRI are negative, careful follow up is recommended as the test can become positive before a lesion is identifiable by these imaging studies

Autoantibodies formed from some cancers can be measured up to 4 years before there is clinical evidence of disease.

ONG: Does this test indicate all types of lung cancer, including mesothelioma?

Dr Jewell: The data so far indicate that all histologic types of lung cancer have an equal chance of being positive with this test. At this time, we do not have enough data to answer the question regarding mesothelioma.

ONG: Is the test something that might be submitted for FDA approval in the future?

Dr Jewell: The Oncimmune laboratory meets all federal and state regulatory standards for performing high-complexity testing, such as is employed with *Early*CDT-Lung, and ensures that the test is performed under the comprehensive quality system required by the CLIA regulations.* Oncimmune falls under the auspices of CLIA accreditation, as the company does not produce a kit or medical device that is shipped to a client, but instead offers *Early*CDT-Lung as a lab service; serum samples are shipped to the lab and assessed. Oncimmune operates a CLIA-certified laboratory in the Kansas City metro area. Oncimmune has not applied for FDA-approval of *Early*CDT-Lung, but may do so in the future if regulations demand this.

ONG: How long does it take to get test results back from the laboratory?

Dr Jewell: The turnaround time from the initial submission of a patient blood sample to the time Oncimmune notifies the laboratory and the participating physician of the results is 1 week in most cases.

*CLIA = Clinical Laboratory Improvement Amendments of 1988, which were enacted by Congress to ensure all US laboratories meet standards of accuracy, reliability, and timeliness. More information on these amendments can be found at www.cms.hhs.gov/CLIA.