Evaluate Vantage

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# Veracyte sets sights on payment for lung cancer test

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Confirmatory testing for lung cancer currently involves either needle or surgical biopsy, procedures that are not just risky but expensive. Veracyte is aiming to save cash as well as lives with its less invasive lung cancer test, and now has positive clinical data on the Percepta diagnostic which ought to position it for widespread reimbursement.

Unfortunately, while Percepta can pick out malignancies well enough, the test suffers from poor specificity, meaning a positive result will still have to be confirmed with biopsy. Nonetheless the company remains confident that the test will be welcomed by pulmonologists, and so do investors, who sent its stock up 15% to $10.63 yesterday.

**Screening**

Currently in the US, yearly lung cancer screening with low-dose CT is recommended for heavy smokers aged between 55 and 80, or those with a history of heavy smoking; around 250,000 such scans are performed each year. If a shadow is seen, the patient undergoes visual inspection of the lungs via bronchoscopy. But in around 40% of cases bronchoscopy fails to produce a clear diagnosis.

These patients must then endure either transthoracic needle biopsy or surgical biopsy. With the former carrying a 15-25% risk of collapsed lung and the latter costing upwards of $20,000, a way of improving the accuracy of bronchoscopy would find acceptance.

This is what Veracyte claims to have shown. Two trials, Aegis I and Aegis II, assessed Percepta's use in testing epithelial cells obtained via bronchoscopy to improve the technique's accuracy.

According to the data published in the NEJM, a total of 639 current or former smokers were assessed in the two trials. Bronchoscopy alone was nondiagnostic for 272 (43%), and invasive procedures were performed after bronchoscopy in 35% of patients with benign lesions.

In Aegis I, Percepta had sensitivity of 88% and specificity of 47%. In Aegis II, the test had sensitivity of 89% and specificity of 47%. Standalone bronchoscopy had sensitivity of 74% and 76% in Aegis I and II, respectively.

Combining the Percepta test with bronchoscopy brought sensitivity to 96% in Aegis I and 98% in Aegis II. Specificity was unchanged, the trials' lead researcher, Avrum Spira of Boston University, said on a Veracyte conference call. Dr Spira was co-founder of Allegro Diagnostics, the originator of the Percepta test which Veracyte acquired last September.

**Intermediate**

Before bronchoscopy, doctors used clinical criteria to divide the patients into risk categories: low, intermediate or high probability of having cancer. It is the intermediate-risk group that represents the target population for Veracyte's test. Among intermediate-risk patients with a non-diagnostic bronchoscopy, the Percepta test had a negative predictive value of 91%; in other words, the test could reliably rule malignancy out.

This ought to be good enough to allow wide adoption of the test among intermediate-risk patients, Dr Spira said, as most pulmonary doctors look for risk of malignancy of less than 10%. Patients with a negative result on the test can thus avoid further invasive biopsy or surgery, instead being monitored with CT scans every three months or so.

But, as Dr Spira acknowledged on the call, the test has a "notable false positive rate". These patients will then need needle biopsy or surgery just as if they had not been tested with Percepta at all.

**Tsunami**

Dan Leonard, an analyst at Leerink, wrote in a note that Percepta could have a market opportunity of $120m per year in the US alone, assuming around 15% of patients in the trials were at intermediate risk of developing

cancer and the test was priced at about $3,000.

Lung cancer screening guidelines changed at the beginning of this year. From early 2015 more than eight million people in the US at high risk for lung cancer became eligible for annual CT scans under new Medicare and private insurance coverage. This means doctors are seeing a “tsunami” of smaller lesions which are hard to diagnose via bronchoscopy, Dr Spira said.

Percepta is currently available at some US hospitals, with the actual sample testing occurring at Veracyte’s Clia-certified laboratory. Leerink analysts are expecting reimbursement for Percepta in 2016 and forecast 2017 revenue of around $4m.

Can Veracyte achieve this? If the intermediate-risk population is around 40,000 patients a year, as Mr Leonard seems to suggest, and if the prevalence of lung cancer is around 25%, as it was in the Aegis trials, that means widespread adoption of the test could allow around 30,000 patients to be ruled out each year.

These patients, who would otherwise have to face transthoracic needle or surgical biopsy, could be switched to watchful waiting instead, saving payers a fortune.

But that is a lot of ifs. And there are other possible snags: for example, like all Clia-waived tests Percepta will be at risk from the planned regulatory changes in the US that could force IVD companies to seek premarket approval from the FDA (*Vantage Point – FDA regulation of lab-developed tests could hurt smaller companies, June 19, 2013*). Approval may be harder to swing than reimbursement unless Veracyte comes up with further clinical data.

In the short term, though, reimbursement for the test in the intermediate-risk population looks reasonably likely.

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