Veracyte CEO Says RNA Sequencing Data Will Drive Future Pharma Deals, Products

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SAN FRANCISCO (GenomeWeb) – Veracyte CEO Bonnie Anderson said this week that the firm's growing database of transcriptome data would help drive future deals with biopharmaceutical companies looking to develop precision medicine therapies as well as help guide the firm's future product development.

During a conference call discussing its second quarter 2018 results on Monday, Anderson noted that the company recognized its first biopharmaceutical services revenue from a partnership it struck with Loxo Oncology in April.

In addition, Veracyte management provided updates on the firm's recently launched products, Percepta and Envisia, as well as its progress on the reimbursement front.

In Q2, Veracyte recognized $500,000 from Loxo Oncology for its Afirma Xpression Atlas test, which Veracyte launched in May. The test is geared toward patients who have already received the Afirma GSC and are either deemed at high or an indeterminate risk for thyroid cancer in order to further refine the risk prediction. It analyzes 761 variants and 130 RNA fusion gene partners across 500 thyroid cancer-associated genes. Under the agreement with Loxo, it will focus on analyzing TRK gene fusions and RET alterations.

Going forward, the firm expects to recognize $250,000 in revenue from Loxo in both Q3 and Q4 this year.

Anderson also anticipates other pharmaceutical companies will be interested in similar such deals. The "rich genomic content" from Afirma Xpression Atlas is of "significant interest to developers of precision medicine therapies," she said.

Due to Veracyte's RNA sequencing strategy, the firm is generating "vast amounts of rich transcriptomic data" from its tests, Anderson said. And although that data is currently being used to "resolve diagnostic uncertainties" in thyroid cancer and idiopathic pulmonology, "we believe it will one day open the door to answering important clinical questions at other points in the clinical care continuum."

Anderson also added that the firm is on track to launch its Envisia Genomic Classifier test for idiopathic pulmonary fibrosis more broadly in 2019 following an early-access program that began in May. Envisia uses RNA sequencing and machine learning to analyze 190 genes, and Veracyte published the clinical validation of the test last year.

The firm delivered its first five patient reports to early-access customers in Q2, and Anderson noted that some users are especially interested in both Envisia and Percepta, a genomic classifier that helps determine whether lung nodules should be surgically removed. "There have been multiple instances in which physicians have adopted Percepta and Envisia together," Anderson said.

In addition, she highlighted several anecdotal examples of how physicians have been using Envisia to enable more confident diagnoses of idiopathic pulmonary fibrosis. In one case, she said, a physician was able to use the more confident diagnosis provided by Envisia to secure health care coverage of a drug that had previously been denied to the patient.

On the reimbursement front, Veracyte has nearly completed the process of securing contracts for individual Anthem plans, following the payor's positive coverage decision last year for the Afirma test, making the test an in-network offering for more than 210 million Americans, Anderson said. In addition, she said, the "in-network status will facilitate coverage and reimbursement for Percepta."

Leerink Analyst Puneet Souda wrote in a note to investors following Veracyte's earnings release that "reimbursement will continue to be an important driver" of revenue, noting that adoption of Percepta will be particularly key to the firm's progress.

An important part of driving adoption and securing reimbursement will likely be clinical utility data. The firm presented interim results from its clinical utility registry study on Percepta at two conferences in Q2. The early results from the study, which includes more than 700 patients at 40 sites, demonstrated that the test can reduce unnecessary surgeries by helping determine whether a lung nodule is benign or at risk for being cancerous. Anderson said that the firm plans to publish the results of the study in a peer-reviewed journal later this year.

As previously announced, the firm is also working on a noninvasive version of Percepta that will classify risk from a nasal swab. Anderson said that the company would discuss early data on that test later this year.

As for additional future products, Anderson said that the company will look at "clinical questions within the indications" it already targets, but it is also open to considering tuck-in acquisitions when they make sense. For instance, she said, its acquisition of Allegro Diagnostics in 2014 is what enabled it to launch Percepta and to move into noninvasive detection of lung cancer via nasal swab.