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Emerging Company Profile

Foundation Medicine: Panoramic profiling

By Erin McCallister
Senior Writer

Current pharmacogenetic tests for cancer are tumor- or mutation-specific, which limits the amount of information that can be gleaned from a single test. **Foundation Medicine Inc.** is creating a single test designed to provide a molecular profile of a range of mutations in any tumor with a single assay. This would reduce the need for multiple tests and could identify additional treatment options for patients.

According to Gary Palmer, SVP of medical affairs and commercial development, most companion diagnostics are specific to a single gene. Thus, if the result is negative, the doctor only knows what drug not to give the patient.

Meanwhile, he noted, MDx tests that look at a panel of genes to provide patient prognoses and guide treatment are specific to a single tumor type.

"Foundation Medicine seeks to take a more panoramic look at the tumor's molecular profile," Palmer said. By looking at hundreds of genes, the company's technique can pick up multiple mutations that no single-gene test can. Foundation's test also works on any tumor type.

President and CEO Michael Pellini said the company's undisclosed DNA extraction technology enables the extraction of enough high-quality DNA for sequencing out of a single sample. He said other technologies fail to produce results about 25-30% of the time. Foundation Medicine's rate is less than 5%.

Foundation Medicine Inc.

Cambridge, Mass.
Technology: Molecular profiling of tumors
Disease focus: Pharmacogenetics
Clinical status: Marketed for research
Founded: 2009 by Eric Lander, Todd Golub, Levi Garraway and Matthew Meyerson
University collaborators: Not disclosed
Corporate partners: Celgene Corp. and Novartis AG
Number of employees: 30
Funds raised: $25 million
Investors: Third Rock Ventures
CEO: Michael Pellini
Patents: None issued

The biotech applies third-party DNA sequencing technology to cancer-related genes. While the latest version of the test analyzes 176 genes, Pellini said Foundation continues to update its gene panel as new data are published or based on advice from advisers and partners.

Once it has sequenced a sample, Foundation uses its algorithms to identify mutations found in the tumor sample compared with the patient's healthy tissue. The company distills this information into a report to help guide treatment, based on how the individual's profile can be linked to a likely treatment response.

According to Pellini, the results fall into three categories: mutations linked to drugs on the market, mutations linked to drugs in development, and "plausibly actionable" mutations. The latter are defined as mutations that might not have a direct link to a drug on the market or in development, but may give additional insight into the disease.

For mutations linked to drugs on the market, doctors could decide which targeted therapy would be best for a patient based on the observed mutations instead of the specific organ from which the tumor originated.

"Rather than looking at it as a colorectal tumor or a non-small cell lung cancer tumor, the doctor can look at is an EGFR or c-Met tumor," Pellini said.

For mutations linked to drugs in development, doctors might recommend the patient enroll in a clinical trial of an agent that targets that specific mutation or set of mutations.

As for plausibly actionable mutations, Pellini said a physician could look at the

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PO Box 1246
San Carlos CA 94070-1246
Voice: 650-595-5333
Fax: 650-595-5589
www.biocentury.com

DAVID FLORES
President & CEO

KAREN BERNSTEIN, Ph.D.
Chairman & Editor-in-Chief

Foundation Medicine,
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literature to find another possible treatment option.

In June, Foundation presented data at the **American Society of Clinical Oncology** (ASCO) meeting in Chicago, showing that of the 176 genes screened, the company's test identified 214 driver mutations in 75 samples of colorectal, NSCLC and melanoma tumors.

Of those 214 driver mutations, only 37 (18%) would have been found using conventional analysis of mutation hot spots. According to Pellini, Foundation's test can look for any sort of aberration in these areas while current tests look only for known mutations.

Furthermore, more than 50% of the tumors in the study contained mutations that could be used to inform treatment decisions. This is significant, Pellini believes, because Foundation found them with a single test and a single tissue sample.

The laboratory developed test (LDT), which takes about two weeks to complete, is available for research use. The test is primarily used by academic labs and biopharma companies to discover cancer-associated biomarkers.

For example, **Celgene Corp.** will be using the test in clinical development to facilitate faster recruitment of target patient populations and to help identify patients who are most likely to respond to its drug candidates.

Foundation also has partnered with **Novartis AG** to conduct a pilot program to develop, enhance and optimize the test for the pharma's needs. If the ongoing pilot is successful, the companies could collaborate on the production and commercialization of the test.

Financial details of the two deals were not disclosed.

The biotech expects to make the test available to physicians in 2012.

Foundation raised $25 million in April.

COMPANIES AND INSTITUTIONS MENTIONED

American Society of Clinical Oncology (ASCO), Arlington, Va.
Celgene Corp. (NASDAQ:CELG), Summit, N.J.
Foundation Medicine Inc., Cambridge, Mass.
Novartis AG (NYSE:NVS; SIX:NOVN), Basel, Switzerland