Oncgnostics Garners €1M to Support Clinical Trials of Epigenetic Cervical Cancer Test

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Premium

NEW YORK (GenomeWeb) – German start-up Oncgnostics recently raised €1 million ($1.1 million) to support clinical trials of an epigenetic assay called GynTect test for assessing cervical cancer risk.

The Jena-based firm raised €500,000 of the money via a crowdfunding mechanism called Seedmatch, with VC group and current investor, Beteiligungsmanagement Thüringen (BM-T) providing matching funds.

Seedmatch is similar to Kickstarter, but only hosts a handful of projects at a time, primarily focused on technology and medicine, Alfred Hansel, Oncgnostics' CEO, told GenomeWeb in an interview.

Oncgnostics acheived its €500,000 crowdfunding target about a week ahead of schedule and within the allotted 60 days, "which is always a good sign," Hansel said.

The company will use the new funding to start two clinical trials of GynTect, Hansel said. One trial will begin this autumn and aims to demonstrate the prognostic value of the test.

So far, the test appears to reduce potentially unnecessary treatment, detecting all cases of cancer but only some of the precancerous stages. "Our guess is that we are only detecting the ones that develop into cancer, whereas other [patients] should not get any surgery or other treatment," Hansel said. "This is something we have to prove directly," he added.

The GynTect test received CE-IVD marking in 2015. It uses epigenetic signatures for cervical cancer risk assessment from smear samples collected in Hologic's PreservCyt liquid-based cytology medium, as well as a method for bisulfite conversion of DNA that Oncgnostics licensed from MDxHealth.

The test uses methylation-specific PCR to detect DNA methylation in five marker genes: DLX1, ITGA4, RXFP3, SOX17, and ZNF671, as well as a control gene.

These genes were chosen by comparing the methylation profile of epithelial cells from HPV16-positive cervical samples with no evidence of disease to cervical carcinoma biopsies, according to a 2014 *PLoS One* study published by Hansel and his colleagues.

For panel development, methylated DNA was enriched by a methylated-CpG island recovery assay and subsequently used in hybridization experiments with genome-wide CpG island microarrays, according to the study. The markers were then evaluated in a set of cervical samples from women seen at an outpatient colposcopy clinic.

In the study, the ZNF671 marker in particular had a 93 percent detection rates for CIN3, or severely abnormal cells, and 96 percent detection rate for carcinoma samples, and this marker was only methylated in six percent of normal cervical tissue samples.

Due to the primer design, the methylation-specific PCR also has the advantage of not amplifying non-methylated DNA, Hansel explained. Even in a highly expressed cancer, a sample will only contain about 20 percent cancer cells, he said, but by targeting aberrant methylation the firm can improve specificity on a high background of normal cells.

Hansel noted that few companies currently include epigenetic markers in commercial products. Specifically, Berlin-based Epigenomics and MDxHealth use them, while Exact Sciences has a test for colon cancer that includes at least one methylation marker.

Qiagen, meanwhile, intends to launch a methylation-based cervical cancer test, as reported by GenomeWeb earlier this year. The firm noted that the test is particularly exciting because it offers high specificity and sensitivity that are absent from competing solutions in the market.

The QIAsure test detects aberrant methylation in the promoter regions of FAM19A4 and mir124-2, areas which are purportedly hyper-methylated in cervical cancers. Qiagen also licensed MDxHealth technology for the test.

Another firm, Neumann Diagnostics in Hungary, deploys an epigenetic marker in its cervical cancer screening test in development by using methylation of the promoter sequence of the POU43 gene in tandem with high-risk HPV strain identification to triage patients for colposcopy and to stratify risk.

Founded in 2012 as a spinoff from the University Women's Hospital in Jena, Oncgnostics currently has eight employees, five of whom are working on both R&D and production of the GynTect kit in the firm's ISO13485 certified workspace, Hansel said.

Oncgnostics is also now planning to develop epigenetics-based tests for ovarian cancer and head and neck cancer.

"There is no good screening in ovarian cancer — there are some markers around that are used but they are of no real benefit because they are present only in late cases," Hansel noted.

Head and neck cancer also has a relationship to cervical cancer, as about 20 percent of head and neck cancers are related to HPV infection.

Relative to the GynTect test, "We have seen there is an overlap in the markers in head and neck cancer, but no overlap at all in the ovarian cancer field," Hansel said, adding, "Maybe that's what makes this field of epigenetic markers so specific, that you really are able to define marker sets for different cancers."

In addition to starting new trials and developing new tests, Oncgnostics is presently working on more publications, demonstrating not only the usefulness of the markers but also of the tests and

kits, said Hansel.

So far, Oncgnostics' tests are not broadly used outside of a research context in the Jena hospital, although the firm has set up a distribution partnership in India and has seen interest in Eastern Europe. In four and half years, Oncgnostics has tested a little more than 2,000 samples, Hansel said, acknowledging that the firm simply needs more data to encourage adoption.

But in the long run, the firm sees the US as "the most attractive market," Hansel said.

Oncgnostics is currently in discussions with firms in the US, and would prefer "big diagnostic players, such as Hologic and Exact Sciences" taking over the GynTect concept and pursuing US regulatory approval, as opposed to having its own subsidy in the US. Alternatively, the test might be picked up by a large commercial lab and run as a CLIA test prior to discussion with the US Food and Drug Administration, Hansel said.

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