MiR Scientific Prepares Launch of First Clinical Cancer Test, Buoyed by New Data

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NEW YORK (GenomeWeb) – MiR Scientific, formerly MiR Diagnostics, hopes to launch its first clinical cancer test within the next year, after spending the last several years conducting validation studies of its technology, which involves analysis of microRNA and other small noncoding RNA (sncRNA) molecules in urine.

Using various panels of these RNAs, coupled with algorithmic predictors, the company has been able to create assays that distinguish individuals with cancer from those without, tests that assess prognosis in cancer patients, and assays that can monitor individuals for disease progression.

Founded in 2012, MiR began as a venture to commercialize discoveries made in Martin Tenniswood's lab at the University of Albany. In its early days, the firm, based in Albany, was focused on developing an assay to be performed on tissue samples from men who have received a prostate biopsy. The test would provide a better alternative to the existing Gleason scoring method, which is used to determine which men can forego treatment in favor of close monitoring.

Since then, the company has demonstrated that it can also obtain this prognostic information noninvasively, from urine, and that it can improve other areas of testing, including screening, early diagnosis, and monitoring.

"Based on Dr. Tenniswood's work, the goal of the company has been to support expanded validation, with the hope that the technology would have broader applicability," said miR CEO Sam Salman.

"Based on the results, we believe it is time to expand," he added. "We think we are at an inflection point where we have enough validation to give us confidence in moving forward."

Although the company started its efforts in prostate cancer, Salman said that bladder cancer will most likely be where it launches its first commercial test, initially under an LDT model, but with long-term plans to also develop and seek FDA approval for kits.

Because the population being screened for bladder cancer is much smaller than that for prostate cancer, the company hopes to get itself up and running operationally as it works behind the scenes to build up capabilities for higher sample volumes in the prostate cancer setting.

"From what we can control in the process, we think we [will be] able to have an LDT operation running in less than 12 months for bladder cancer," Salman said.

"For prostate, we need to be able to scale, and we need innovations in the operation of the tests, so we are working with a leading developer of LDT labs to create that innovation," he added. The company has not yet named that partner.

Toward future FDA submissions, the company has hired experts to help guide its longer-term strategy.

As it advances its larger suite of tests, MiR will enter competition with several existing companies, but none, according to Salman, that addresses the continuum of testing that MiR hopes to service.

Prostate cancer diagnosis, for example — distinguishing which men who have clinical signs of disease need to have a biopsy, and which can safely forgo it — has been the object of much interest as the limitations of tools like prostate-specific antigen (PSA) have become more widely recognized.

Men with high PSA may or may not actually have a malignancy, and the lack of tools to stratify patients has led to vast overuse of biopsies, which are costly and associated with infection and other risks.

Tests that have already been launched to address this unmet need include MDxHealth's assay SelectMDx. Exosome Diagnostics also markets a urine-based test called ExoDx Prostate (IntelliScore), intended to help clinicians determine whether a patient with an ambiguous PSA test needs a prostate biopsy.

Where prostate cancer prognosis is concerned, MDxHealth also has a stake, offering a tissue-based assay called ConfirmMDx that is designed to help reduce unnecessary repeat biopsies.

For later disease stages, tests have been launched by Genomic Health and Myriad Genetics for assessing prognosis and guiding treatment decisions in men who have had a prostatectomy.

Bladder cancer has also been targeted by MDxHealth, with its AssureMDx assay, which is designed to help identify which patients need cystoscopy and which can avoid it.

According to Salman, MiR intends to distinguish itself from these other players by offering a single platform that can comprehensively serve different needs at the full spectrum of clinical time points from screening through diagnosis and treatment of cancers.

"The goal for the company … is really to create a platform for the management of different cancers, starting with prostate and bladder, that is useful across the full process of cancer management — from diagnosis, to monitoring, prognostics, active surveillance, and in the future, also companion diagnostics and prediction of therapy benefit," he said.

That said, Salman also expressed confidence that MiR will be able to compete in terms of sensitivity and specificity in each of these niches.

"From our point of view, the field really needs a common platform and a technology with interoperable data across the care paradigm," he said. "But in terms of sensitivity and specificity, we also feel, even just based on the data we have released so far, that we are more than able to compete just in terms of accuracy."

At the annual meeting of the American Society for Clinical Oncology earlier this year, MiR researchers presented a poster on the company's assay for monitoring bladder cancer patients post-surgery.

Investigators collected urine samples from 82 patients previously treated for bladder cancer, who were being followed with routine cystoscopies, and compared them to controls in order to develop an sncRNA signature specific for bladder cancer.

In a small blinded testing set, the resulting "miR-BCPx score" could identify patients with recurrent tumors with 100 percent sensitivity and 96 percent specificity.

The company also submitted an abstract for the meeting describing updated validation data for its urine-based prostate cancer diagnostic.

For that study, investigators sampled urine from 107 men with biopsy-confirmed prostate cancer and 21 controls and compared their sncRNA profiles to develop a classifier. They then used this to screen a second independent patient cohort with unknown cancer status, designed to mimic prospective prediction of disease status.

According to the authors, their "miR-PDx score" correctly identified patients with prostate cancer with a specificity of 95 percent and a sensitivity of 99 percent.

Tenniswood said that that the presentations represent just a small fraction of the data the company has collected and is now poised to collect, with cohorts that total around 5,000 individuals in both New York and Canada, where the company has collaborators.

The firm is now working on larger investigations of the prostate cancer diagnostic application, which are being designed in collaboration with researchers at SUNY Downstate Medical Center to answer important questions about the robustness of the test across different ethnic or racial populations.

Researchers will also expand validation of the company's panels for prognostic assessment, and look at the use of technology in active surveillance.

A similar set of studies is planned in bladder cancer, focused on the main needs for that setting, which are the screening of patients with clinical signs of cancer, like blood in the urine, and the noninvasive monitoring of patients after surgery to avoid near-constant cystoscopies, which are the current standard of practice.

Salman said that the firm is also setting up clinical study protocols for similar efforts outside of North America — in Europe, Asia, and Israel.

He added that the company plans to announce a strategic alignment with a major platform company soon but did not disclose the partner. So far, the company's tests have been developed using Affymetrix and Thermo Fisher array technologies.