MiR Scientific Prepares to Launch Tests for Prostate, Bladder Cancer

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NEW YORK (GenomeWeb) – After presenting initial validation data on a prostate cancer microRNA-based urine assay that is designed to aid diagnosis, provide prognosis, and monitor disease progression, MiR Scientific believes it is prepared to launch tests for both bladder and prostate cancer by the end of this year or early next.

Formerly called MiR Diagnostics, the company crystalized a diagnostics strategy last summer after several years of research to identify panels of microRNAs and other small noncoding RNAs (sncRNA) that can distinguish cancer from non-cancer, measure disease aggressiveness and prognosis, and monitor future changes or progression.

Last year, the firm was anticipating that bladder cancer, where it had collected more data, would lead its product commercialization. Investigators presented a poster at the 2018 American Society for Clinical Oncology annual meeting on the firm's development of an sncRNA signature that could identify which patients who present to a urologist with a troubling symptom should go on to have a more invasive cystoscopy, and which patients could avoid the procedure.

Sam Salman, MiR Scientific's CEO and chairman, said this week that since then, the company's work in prostate cancer has caught up such that the firm believes it has sufficient data to launch tests for both types of cancer. In the meantime, it is working toward certification for its lab to begin offering commercial testing either later this year or early next.

Importantly, while the firm's bladder cancer application is more binary — assessing the presence or absence of aggressive disease — its goal for prostate cancer was not limited to diagnosis, a setting where several other noninvasive molecular tests have now been advanced, including MDxHealth's SelectMDx and Exosome Diagnostics' urine-based ExoDx Prostate.

Instead, MiR Scientific hopes to position its assay as one that can screen, diagnose, and also measure cancer aggressiveness, make a prognosis, and monitor individuals for changes over time.

"We were very interested in creating a platform with interoperable screening, diagnostic, prognostic, and monitoring capabilities, and this is exactly what we have been able to validate," Salman said.

Also in contrast to its position last year, MiR has now validated its test on a "production platform," that works for both assays, moving the tests to Thermo Fisher Scientific's OpenArray technology.

Salman said the company is currently preparing a paper that provides more details on its prostate cancer expression signature, which includes hundreds of microRNA and snoRNA (small nucleolar RNA) sequences isolated from urinary exosomes. This will include more

granular data on the ability to distinguish between cancer grade groups and will hopefully appear in the peer-reviewed literature by this summer, he said.

In the meantime, company researchers recently shared some limited data on what MiR is now calling its "MiR Scientific Sentinel Scores" in a poster presentation at the European Association of Urology Congress, assessing the test's ability to distinguish between clinically significant prostate cancer (grade group 2 through 5) and non-cancer (grade group 1 or non-cancer samples).

Investigators reported that they identified the assay signature by using MiR Scientific's proprietary algorithmic classification method on a training data set of 235 patients with known pathology and clinical outcomes. The resulting "PCa Sentinel Score" was then validated in 146 patients whose grade group (GG) was confirmed by histopathology. According to the abstract, the test correctly identified 87 of 88 patients with GG1 tumors — a negative predictive value over 98 percent — and classified 55 of 56 patients with clinically significant cancer, GG2 to GG5 — a positive predictive value greater than 98 percent.

As it prepares to launch the tests commercially, MiR is taking steps now to have its lab certified under the New York State Department of Health's Clinical Laboratory Evaluation Program (CLEP).

"We are in the midst of basically going through the process of hiring and positioning and buying … to set up for that LDT [provision] for both prostate and bladder [cancer]," Salman said.

He also said that the company has made agreements with a larger number of unnamed institutions, in the US and internationally, to perform clinical validation studies of the Scientific Sentinel Scores methodology. These will hopefully provide definitive proof for the sensitivity and specificity of the platform for both the prostate and bladder cancer indications, as well as collect data on clinical impact and health economics that will be crucial for obtaining insurance reimbursement.

The company is funded sufficiently for its goals as they stand, Salman added. However, MiR Scientific believes there would be strategic value to work toward a "platform alignment" in the next few years, he said, which could support translation of its approach from the LDT setting to a disseminated kit model.