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ASIA EDITION

Singapore to translate microRNA research into clinical applications

January 29, 2020 | News

Singaporean biotech start-up MiRXES collaborates with NUS and DxD Hub of Astar spearhead three initiatives to the forefront of global microRNA research into clinical applications



MiRXES, a leading Singaporean biotech start-up in microRNA (miRNA) technology and diagnostics, collaborated with NUS and DxD Hub to mark the tenth year of miRNA research and clinical translation in Singapore. These organizations jointly led a non-coding RNA (ncRNA) Symposium to advance research in miRNA and other ncRNAs, a ncRNA Roundtable to chart a strategy for miRNA clinical translation globally, and Working Group for miRNA standards that will provide the world's first national (Singapore) standard for miRNA-based diagnostics by this year.

These landmark meetings, held in January 2020, pave the way for more reliable clinical validation and greater industry adoption of miRNA-based diagnostics, both nationally and globally. These initiatives also place Singapore at the forefront of translating miRNA research into new diagnostic applications that will improve disease diagnosis and treatment outcomes globally.

Using miRNA to address healthcare and health issues

MiRXES and NUS co-organized the inaugural ncRNA Symposium on 6 January 2020, where international experts presented ground-breaking research in miRNA-based diagnostics and therapeutics. Key symposium speakers included MiRXES Scientific Advisory Board members Prof. Frank Slack, director of the Harvard Medical School Initiative for RNA Medicine; Prof. Yeoh Khay Guan, Chief Executive of the National University Health System in Singapore; and Prof. Takahiro Ochiya, leader of Japan's national miRNA cancer diagnostics project.

Prof. Slack co-discovered the first human miRNA in 2000 and brought about a paradigm shift in how the scientific community views miRNAs and other ncRNAs. Early studies on ncRNAs considered the genetic material as "junk RNA", with little awareness of the critical role they play in gene regulation.

"There is growing scientific evidence that non-coding RNA molecules such as miRNAs have the potential to change the way we diagnose and treat diseases in the near future," said Prof Slack.

Symposium speakers also participated in the ncRNA Roundtable co-chaired by Dr. Sidney Yee, CEO of DxD Hub, and Dr. Zhou Lihan, Co-Founder and CEO of MiRXES, on 7 January 2020. Roundtable discussions centred on using miRNA

technology to address global healthcare and health issues relevant to Singapore. These include the increasing burden of cancer and chronic diseases such as diabetes and heart disease, along with other health issues that come with an ageing population.

"Bringing academic researchers, clinicians, industry players, and government regulators together in such discussions will help in accelerating adoption of clinically-validated miRNA-based diagnostics and therapeutics," said Dr. Zhou.

The 2020 ncRNA Symposium and Roundtable marked a ten-year milestone of translational miRNA research since the first publication in 2010 of the scientific method that is the basis of the MiRXES technology platform. The industry-leading miRNA detection technology has been applied by MiRXES globally to study and develop diagnostic applications for more than 30 different diseases, including more than 10 different cancer types, heart disease, and diabetes. MiRXES is on track to complete the world's largest miRNA expression database from 200,000 clinical samples across 30 types of diseases in the next five years.

"We're proud of the progress that the biomedical industry and homegrown enterprises such as MiRXES have made in the field of miRNA research. We look forward to more public-private partnerships that will accelerate the development of new diagnostics to establish Singapore as a global hub for diagnostic innovation and development, and address the burden of unmet clinical needs," said Dr. Yee.

Standardizing the reliability of miRNA-based diagnostic products

One key to accelerating the development of new miRNA-based diagnostics is to ensure the reliability of products through standardization. This is the aim of the Working Group for miRNA standards set up by the Singapore Standards Council. The Working Group comprises representatives from MiRXES, DxD Hub, Health Sciences Authority (HSA), academia, industrial, and clinical sectors.

The group gathered on 7 January 2020 to draft the world's first national standard for validation of miRNA-based diagnostics, putting it on-track for approvals and publication this year. The miRNA standard will include specifications and procedures that make it easier for users and regulators to understand and compare competing miRNA-based diagnostic products.

"The development of this standard will ensure quality consistency in the collection, handling and isolation of miRNAs from human samples. This will facilitate greater regulatory approval, boost patients' confidence in diagnostics accuracy and enable quicker access to treatment for chronic diseases. Companies can use this standard to develop new test kits for diseases, such as cancers, based on miRNA techniques. We will work with industry stakeholders and regulators to support greater innovation and commercialization of new products and services in the biomedical sector," said Dr. Yong Chern Chet, Chair of the Biomedical and Health Standards Committee, Singapore Standards Council.

Singapore's efforts in leading the development of miRNA on a global stage

Homegrown biotech firms such as MiRXES are making great strides in elevating Singapore to the forefront of the global miRNA industry thanks to supporting from regulatory authorities. Singapore achieved a world's first in 2019 when HSA approved GASTROClear, a miRNA-based *in vitro* diagnostic solution for early detection of gastric cancer. As co-developer and manufacturer, MiRXES consulted HSA several times during the product development phase of GASTROClear. Early consultation with HSA enhanced MiRXES's understanding of the regulatory requirements and facilitated the approval process.

After receiving regulatory approval from HSA for GASTROClear *via* the priority review pathway, MiRXES is poised to take on a leading role on the global stage in guiding innovative miRNA discoveries towards clinical validation and application. The expanding start-up, which was Singapore's fastest-growing health sector company between 2015 and 2018, recently set up a new office for its research and development team in Biopolis to accommodate its rapid growth.