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ASIA EDITION

Mirxes receives US FDA's Breakthrough Device Designation for blood-based cancer detection test

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GASTROClear is the first miRNA blood test and the first gastric cancer molecular test globally to receive FDA Breakthrough Device Designation



Mirxes Corporation USA, the wholly owned subsidiary of Mirxes Pte Ltd, a Singapore-headquartered RNA technology startup, has announced that its flagship product GASTROClear™, a PCR-based in vitro diagnostic test for early detection of gastric (stomach) cancer, has been granted Breakthrough Device Designation by the US Food and Drug Administration (FDA).

Globally, this marks the first time that 1) a blood miRNA test, 2) an in vitro diagnostic (IVD) test for early detection of gastric cancer, and 3) a molecular in vitro diagnostic test developed in Southeast Asia, has received a Breakthrough Device Designation from the US FDA. This designation is only granted to certain medical devices that address unmet needs and provide more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions such as cancer.

Launched in 2019, GASTROClear™ is the world's first molecular blood test for the early detection of gastric cancer, enabling physicians and patients to act early before symptoms occur. GASTROClear™ was developed and manufactured in Singapore through a seven-year public-private partnership by physicians and scientists at the Agency for Science, Technology, and Research (A*STAR)'s Bioprocessing Technology Institute (BTI), Diagnostics Development Hub (DxD Hub), the Singapore Gastric Cancer Consortium (SGCC), the National University of Singapore (NUS), the National University Hospital (NUH), Tan Tock Seng Hospital (TTSH) and Mirxes.

GASTROClear™ was first approved by the Singapore Health Science Authority (HSA) in 2019, after a prospective clinical validation in more than 5,200 patients in Singapore. More recently, Mirxes, in collaboration with seven academic clinical institutions in China, conducted a large prospective clinical trial involving more than 9,000 patients, for registration of GASTROClear™ with China's National Medical Product Administration (NMPA). Post-pandemic, Mirxes is making GASTROClear™ accessible in key Asia Pacific markets and is evaluating partnership to enable its launch in the United

States.

GASTROClear™ is currently available in Southeast Asia, including Singapore, Indonesia, Malaysia and Philippines.