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Mirxes' non-invasive microRNA blood test secures approval in China for gastric cancer screening

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GASTROClearÃ¢â??Â¢ is the world's first approved microRNA (miRNA) blood test for the early detection of gastric cancer



Mirxes, a leading and only publicly-listed molecular cancer early detection company in Asia Pacific, has been granted regulatory approval for its flagship product, GASTROClear™, by China's National Medical Products Administration (NMPA). The test is the first non-invasive blood test approved in China for screening gastric cancer as an *in vitro* diagnostic (IVD) test.

A prospective clinical trial by Mirxes in China enrolled 9,472 subjects across seven leading academic clinical institutions between December 2021 and November 2023, making it one of the largest of its kind in the world. The clinical trial demonstrated that the test accurately detects early-stage gastric cancer in the Chinese population. According to China's 2024 Guideline for Gastric Cancer Screening, Early Diagnosis and Intervention, the GASTROClear™ blood test is approved for screening gastric cancer in adults aged 45 to 74 who are at high risk for the disease.

The NMPA's approval will enable Mirxes to significantly scale up the commercialization of GASTROClear™ in China. By 2026, the company intends to triple its sales team, upgrade its manufacturing facilities, and expand its distribution channels throughout the country in anticipation of growing demand.

As demonstrated in clinical trials, GASTROClear™ is superior to existing biomarkers and performs similarly to gastroscopy in terms of clinical effectiveness. As the world's first approved microRNA (miRNA) blood test for the early detection of gastric cancer, GASTROClear™ assesses gastric cancer risk by measuring a panel of 12 gastric cancer associated miRNAs from a single blood draw.With proven 87.5% sensitivity for Stage 1 cancers and 75% sensitivity for lesions under 1 cm, GASTROClear™ has set a new benchmark in blood-based cancer early detection.

Following its regulatory approval in Singapore in 2019 and having received the US Food and Drug Administration (FDA) Breakthrough Device Designation in 2023, GASTROClear™ is now approved in multiple countries, offering a safe and effective alternative to traditional screening methods, which is particularly beneficial for older individuals and those with physical or medical limitations.

"The approval marks a significant milestone in our mission to provide accessible cancer screening solutions in China and across Asia-Pacific. Mirxes is bringing life-saving technology to hundreds of millions of people in China at high risk of gastric &

cancer” said Dr Zhou Lihan, Co-Founder and CEO of Mirxes.