

Singapore's Mirxes Announces NMPA Approval for GASTROClear™ in China, Paving the Way for Major Launch in Key Market

GASTROClear™ is the first non-invasive blood test approved for the screening of gastric cancer in China; Mirxes plans major expansion of operations in China

SINGAPORE, SINGAPORE, SINGAPORE, October 10, 2025 /EINPresswire.com/ -- [Mirxes](#), a leading and only publicly-listed molecular cancer early detection company in Asia Pacific, announced that its flagship product, [GASTROClear™](#), has been granted regulatory approval by China's National Medical Products Administration ([NMPA](#)) as an in vitro diagnostic (IVD) product, becoming the first non-invasive blood test approved for the screening of gastric cancer in China.



GASTROClear is now approved for use as an in vitro diagnostic (IVD) product in China.

To secure the NMPA approval, Mirxes successfully conducted and completed one of the world's largest prospective clinical trials of its kind in China between December 2021 and November

2023, enrolling 9,472 subjects across seven leading academic clinical institutions in the process. The clinical trial provided robust data demonstrating the test's ability to accurately detect early-stage gastric cancer in the Chinese population. China's NMPA has approved GASTROClear™ blood test for gastric cancer screening in adults aged 45 to 74 who are at high risk for the disease, as defined in the 2024 edition of China Guideline for Gastric Cancer Screening, Early Diagnosis and Intervention. This represents an eligible screening population estimated to be over 500 million.

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The NMPA's decision allows Mirxes to bring this life-saving technology to hundreds of millions of people in China at high risk of gastric cancer.”

*Dr. Zhou Lihan, Co-Founder
and CEO of Mirxes*

The Chinese market presents a tremendous opportunity for GASTROClear™, driven by the country's high incidence of gastric cancer and government initiatives aimed at enhancing cancer screening. This landmark approval will also allow public and private health institutions in China to offer GASTROClear™ as an IVD test to their patients.

According to data from Frost & Sullivan, the market size for gastric cancer screening in China, Japan, Southeast Asia, and the United States has increased from US\$13.0 billion in 2019 to US\$15.2 billion in 2023, and is expected to exceed US\$25.0 billion by 2033. Furthermore, the penetration rate of gastric cancer screening among high-risk populations in China has risen from 21.6% in 2019 to 27.8% in 2023, and is projected to reach 67.0% by 2033, surpassing Japan's rate of 61.4%, which indicates enormous market potential.

With the NMPA's approval, Mirxes will significantly scale up the commercialization of GASTROClear™ in China. The company plans to rapidly triple its sales team by 2026 and, in anticipation of growing demand, will also upgrade its manufacturing facilities and expand its distribution channels across the country.

GASTROClear™ has proven its superior performance in clinical trials, surpassing existing biomarkers and demonstrating clinical performance comparable to gastroscopy. 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 a 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.

"This approval marks a significant milestone in our mission to provide accessible cancer screening solutions in China and across Asia-Pacific. The NMPA's decision allows us to bring this life-saving technology to hundreds of millions of people in China at high risk of gastric cancer. This is a deeply rewarding moment for the Mirxes team and our clinical partners in China, Singapore and Japan, as it validates close to a decade of hard work we've dedicated not just to creating a great product, but to ensuring it is accessible to those who need it most," said Dr. Zhou Lihan, Co-Founder and CEO of Mirxes.

"The journey to this milestone has been the culmination of years of dedicated research and clinical trials, including the massive prospective registrational trial in China. We are confident in the ability of GASTROClear™ to advance gastric cancer screening in China with its superior clinical performance and patient-friendly approach," added Dr. Zou Ruiyang, Co-Founder and

CTO of Mirxes.

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