Genetron Health Receives CE Mark for 8-Gene Lung Cancer Assay and Provides FDA Reference Panel Comparative Data of its SARS-CoV-2 RNA Test

July 13, 2021

The CE Mark and comparative data highlight the Company's capability in providing high quality and consistent testing products

BEIJING, July 13, 2021 (GLOBE NEWSWIRE) -- Genetron Holdings Limited ("Genetron Health" or the "Company", NASDAQ:GTH), a leading precision oncology platform company in China that specializes in molecular profiling tests, early cancer screening products and companion diagnostics development, today announced that it has received CE Mark for its 8-gene Lung Cancer Assay. Separately, the Company also reported comparative data showing the sensitivity performance of the Genetron SARS-CoV-2 RNA Test.

The CE Mark represents the second regulatory milestone for 8-gene Lung Cancer Assay, as it is already approved by China's NMPA and is being commercialized in China. This product is based on the Company's proprietary One-Step Seq Method, offering fast and easy-to-use testing procedures, that is suitable for independent operation within hospitals. With the One-Step Seq technology, the library construction process is finished in one step of reaction, minimizing manual operation to one mixture of reagents with DNA/cDNA. The chance of contamination in the process is minimal with the "sample in library out" workflow. The assay is compatible with the Genetron S5 sequencing platform, and together they offer a two-day turnaround time from sample to report. The 8-gene Lung Cancer Assay covers mutations of EGFR, BRAF, KRAS, HER2 and PIK3CA, translocations of ALK and ROS1, and MET exon 14 skipping, and 7 of these genes are recommended biomarkers by the 2018 NCCN guideline for Non-Small Cell Lung Cancer (NSCLC) patients. Several targeted therapy drugs such as Gefitinib, Osimertinib, Crizotinib and Savolitinib have been approved by the NMPA for treatments of NSCLC patients with those genomic alterations.

"We are excited to receive the CE Mark, which represents an important new commercialization opportunity for our 8-gene Lung Cancer Assay. Together with our Genetron S5 and fully automated bioinformatics solutions, we offer an end-to-end, fast turnaround and seamless workflow for hospitals and clinical laboratories that prefer to run NGS testing on their own. We believe that this offers a significant operational advantage for our customers outside China and we have received very positive feedback since launching in China," said Sizhen Wang, Co-founder and CEO of Genetron Health.

Separately, the Company also reported comparative performance data of its SARS-CoV-2 RNA Test based on a SARS-CoV-2 reference panel established by the U.S. Food and Drug Administration (FDA). The goal of the reference panel is to allow for a more precise comparison of the analytical performance of different molecular in vitro diagnostic (IVD) assays intended to detect SARS-CoV-2. Results from the blind testing of this panel showed that the sensitivity or limit of detection (LoD) of Genetron's SARS-CoV-2 RNA Test was 1,800 NDU/mL, which was the best among all domestic companies in China in the same category, and also fared well compared to global companies. Background information, and peer data, regarding this FDA reference panel initiative can be found on the FDA website.

In June 2020, Genetron Health received Emergency Use Authorization (EUA) from the FDA for its independently developed SARS-CoV-2 RNA Test for the novel coronavirus. Additionally, the kit received approval for export from the relevant authorities in China (Press Release).

Mr. Wang continued, "We have supplied this test to various high-risk geographies around the world since the beginning of the pandemic. This FDA initiative allows us to fairly compare our product with other manufacturers, and we are pleased that we have achieved the best performance among the domestic companies, which further demonstrates our company's capability and commitment to providing high-quality molecular diagnostic solutions."

About Genetron Holdings Limited
Genetron Holdings Limited ("Genetron Health" or the "Company") (Nasdaq:GTH) is a leading precision oncology platform company in China that specializes in cancer molecular profiling and harnesses advanced technologies in molecular biology and data science to transform cancer treatment. The Company has developed a comprehensive oncology portfolio that covers the entire spectrum of cancer management, addressing needs and challenges from early screening, diagnosis and treatment recommendations, as well as continuous disease monitoring and care. Genetron Health also partners with global biopharmaceutical companies and offers customized services and products. For more information, please visit ir.genetronhealth.com.

Safe Harbor Statement
This press release contains forward-looking statements. These statements are made under the "safe harbor" provisions of the U.S. Private Securities Litigation Reform Act of 1995. Statements that are not historical facts, including statements about the research results and genomic research, Company's One-Step Seq Method, studies on optimizing clinical routine diagnosis methods are forward-looking statements. Forward-looking statements involve inherent risks and uncertainties, and a number of factors could cause actual results to differ materially from those contained in any forward-looking statement. In some cases, forward-looking statements can be identified by words or phrases such as "may", "will," "expect," "anticipate," "target," "aim," "estimate," "intend," "plan," "believe," "potential," "continue," "is/are likely to" or other similar expressions. Further information regarding these and other risks, uncertainties or factors is included in the Company's filings with the SEC. All information provided in this press release is as of the date of this press release, and the Company does not undertake any duty to update such information, except as required under applicable law.

Investor Relations Contact
US:
Hoki Luk
Head of Investor Relations
Email: hoki.luk@genetronhealth.com

Phone: +1 (408) 891-9255

David Deuchler, CFA
Managing Director | Gilmartin Group
ir@genetronhealth.com

Media Relations Contact
Yanrong Zhao
Genetron Health
yanrong.zhao@genetronhealth.com

Edmond Lococo
ICR
Edmond.Lococo@icrinc.com
Mobile: +86 138-1079-1408
genetron.pr@icrinc.com