Genetron Health Receives CE Mark for FusionScan Plus Kit for Human Multi-Genes

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BEIJING, June 01, 2022 (GLOBE NEWSWIRE) -- Genetron Holdings Limited (“Genetron Health” or the “Company”, Nasdaq: GTH), a leading precision oncology platform company in China that specializes in offering molecular profiling tests, early cancer screening products and companion diagnostics development, today announced it has obtained a CE Mark for its FusionScan Plus Kit, an integrated DNA and RNA NGS-based assay for simultaneously detecting multiple gene mutations and fusions with lower thresholds, (Registration number: DE/CA20/01-IVD-Luxuslebenswelt-886/22).

Receipt of the CE Mark is an important step for the acceleration of FusionScan Plus’s global footprint, and its potential to enter more international clinical trials in the future.

Based on Genetron Health’s One-Step™ Seq Method, FusionScan Plus covers 29 tumor-related mutant genes, and 40 fusion genes. FusionScan Plus breaks through the limitations of traditional detection methods. With lower threshold requirements and a faster process, it can simultaneously detect sensitive or drug-resistant gene mutations at the DNA level, and the known and unknown partner genes fusions at the RNA level, in tumor tissue samples. It can provide an effective reference for clinical pathological classification, formulation of targeted treatment strategies and new drug development.

Genetron Health revealed the study results on FusionScan Plus at the Association for Molecular Pathology 2021 Annual Meeting. The detection results of 76 clinical formalin-fixed paraffin-embedded (FFPE) samples proved that FusionScan Plus shows high accuracy in the detection of gene mutations and fusions without a priori knowledge of 5’ fusion partner. It can accurately detect drug sites for cancer patients and screen the population for targeted therapies, even with limited biopsy samples, thus improving the clinical benefits of patients.

Genetron Health has been actively promoting the clinical validation and business distribution of multiple IVD products in domestic and overseas markets. Currently, Human IDH1 Gene Mutation Detection Kit (PCR-fluorescent probe method), Human TERT Gene Promoter Mutation Detection Kit (PCR-fluorescent probe method), Human 8-Gene Mutation Joint Detection Kit (semiconductor sequencing method), Human 825 Gene Mutation Detection Kit (combined probe-anchored polymerization sequencing method), Human B Lymphocyte Minimal Residual Disease Detection Kit (reversible termination sequencing method) and other products have successively obtained the EU’s CE mark. In the future, the Company will closely follow the clinical needs of molecular detection, accelerate the commercialization of products, and provide patients with more precise and accessible medical services.

About CE Mark

The CE mark stands for CONFORMITE EUROPEENNE, a security-certified mark, and is seen as a passport for manufacturers to open and enter the European market. In the EU market, the CE mark is a compulsory certification mark, whether it is a product produced within the EU enterprise or a product produced in other countries. In order to circulate freely in the EU market, a CE mark must be added to indicate that the product meets the basic requirements of the EU. For more information:
https://europa.eu/youreurope/business/product-requirements/labels-markings/ce-marking/index_en.htm

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 Company’s beliefs and expectations, 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.

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