Genetron Health Receives CE Mark for Human B Lymphocyte Minimal Residual Disease Detection Kit Seq-MRD®

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BEIJING, April 19, 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 received a CE Mark for its proprietary Human B Lymphocyte Minimal Residual Disease Detection Kit (Reversible Termination Sequencing Method), which is also known as Seq-MRD® (Registration Number: DE/CA20/01-IVD-Luxuslebenswelt-190/22).

Based on high-throughput next generation sequencing (NGS) technology, Seq-MRD® assay is intended to test the CDR3 regional sequence of the IgH/K/L gene of the B cell receptor (BCR) in bone marrow samples collected from patients with B lymphpocytic leukemia (B-ALL/CLL) and multiple myeloma (MM) before and after the treatment. By screening out significant and specific clonal rearrangement form in a patient's tumor cells, this approach can detect minimal residual disease and provide a reference for the follow-up treatment of cancer survivors.

The Seq-MRD® assay has been optimized with Genetron Health’s “One-step Seq Method” technology, which enables the DNA library construction process for gene sequencing to finish with a single PCR and minimizes the risks of sample contamination and false positive results. This simple operational feature, combined with the Company’s automated bioinformatics analysis solution, enables Seq-MRD ® to have broad application prospects due to its key technological advantages of high throughput, fast turnaround, stability and accuracy, and high cost-efficiency. Recently, an experiment was completed that identified the assay performance in various perspectives, such as sensitivity, accuracy, specificity and precision, among which, 128 clinically confirmed samples showed a high concordance on positive detection results from the Seq-MRD® assay and the traditional technology of flow cytometry (FCM). More importantly, there were 10 samples detected as positive by Seq-MRD® assay, which were identified as negative by FCM, demonstrating the higher sensitivity of the assay.

In October 2021, Genetron Health and Jiangsu Fosun Pharmaceutical Sales Co., Ltd (“Jiangsu Fosun Pharma”) signed an exclusive Seq-MRD ® commercialization agreement. With Jiangsu Fosun Pharma’s sizeable, experienced, hematologic cancer focused sales force, the two sides have been working together to co-market and co-promote Seq-MRD® in hematologic-focused hospitals and clinics across designated territories in China, to meet the clinical testing needs of patients with lymphatic hematological tumors.

In addition to Seq-MRD®, Genetron Health is also actively promoting the clinical validation and business plan 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) and other products have successively obtained 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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