Genetron Health Announces Companion Diagnostic Collaboration Agreement with HUTCHMED's ORPATHYS® for NSCLC

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BEIJING, Feb. 10, 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 that it has signed a collaboration agreement with HUTCHMED Limited ("HUTCHMED") (Nasdaq/AIM: HCM; HKEX: 13) for the joint development of a companion diagnostic (CDx) test for ORPATHYS® (savolitinib) in China.

Under the agreement, the partners plan to jointly validate and register Genetron Health's approved NGS-based 8-gene Lung Cancer Assay (Tissue) as CDx for ORPATHYS®. Developed based on Genetron Health's proprietary One-step Seq method, the 8-gene Lung Cancer Assay (Tissue) was approved by China's National Medical Products Administration ("NMPA") as an IVD assay in 2020. This assay is the first approved NGS-based panel for non-small cell lung cancer (NSCLC) on the market that could detect RNA-based MET exon 14 skipping alterations for therapy selection and monitoring. The assay has been commercialized in China for use in hospitals and has also obtained CE Mark in 2021.

ORPATHYS® is an oral, potent, and highly selective MET tyrosine kinase inhibitor ("TKI") that has demonstrated clinical activity in advanced solid tumors. It blocks atypical activation of the MET receptor tyrosine kinase pathway that occurs because of mutations (such as exon 14 skipping alterations) or gene amplification. Following a priority review, ORPATHYS® was granted drug registration conditional approval by the NMPA in China in June 2021.

More than a third of the world's lung cancer patients are in China and, among those with NSCLC, approximately 2-3% have tumors with MET exon 14 skipping alterations, a targetable mutation in the MET gene.[1-3] This mutation is more common (13-22%) among patients with pulmonary sarcomatoid carcinoma (PSC), a rare and aggressive subtype of NSCLC usually resistant to chemotherapy.[4-5]

Dr. Weiguo Su, Executive Director and Chief Scientific Officer of HUTCHMED, said, "We are delighted to work with Genetron Health, a leading precision oncology molecular diagnostic player in China. CDx test is becoming a valuable tool for the use of ORPATHYS® in the clinical setting for NSCLC patients harboring MET exon 14 skipping alterations. We look forward to developing this diagnostic solution with Genetron Health to allow more patients to benefit from this innovative therapy."

"ORPATHYS® represents another important treatment option for NSCLC patients in China, and we are very excited to partner with HUTCHMED to further develop our Lung 8 assay as their first RNA-based NGS companion diagnostics product for this novel drug," said Sizhen Wang, co-Founder and CEO of Genetron Health. "This partnership represents another major CDx partnership for us and upon approval, we expect this to further increase Lung 8's penetration into China's top hospitals. As precision medicine and targeted therapeutics continue to gain traction in China, we continue to expect CDx development to follow suit. CDx remains a big focus for Genetron, and we are committed to exploring more ways to develop innovative products to benefit more patients," Wang said.

Reference:

[1] Vuong HG, et al. Clinicopathological implications of MET exon 14 mutations in non-small cell lung cancer – A systematic review and meta-analysis. Lung Cancer 2018; 123: 76-82. doi: 10.1016/j.lungcan.2018.07.006.

[2] World Health Organization. International Agency for Research on Cancer. Lung Fact Sheet. Available at https://gco.iarc.fr/today/data/factsheets/cancers/15-Lung-fact-sheet.pdf. Accessed June 2021.

[3] World Health Organization. International Agency for Research on Cancer. Globocan China Fact Sheet 2020. Available at http://gco.iarc.fr/today/data/factsheets/populations/160-china-fact-sheets.pdf. Accessed June 2021.

[4] Liu X, et al. Next-generation sequencing of pulmonary sarcomatoid carcinoma reveals high frequency of actionable MET gene mutations. J Clin Oncol 2016; 34: 794-802. doi: 10.1200/JCO.2015.62.0674.

[5] Lu S, et al. Once-daily savolitinib in Chinese patients with pulmonary sarcomatoid carcinomas and other non-small-cell lung cancers harbouring MET exon 14 skipping alterations: a multicentre, single-arm, open-label, phase 2 study. Lancet Respir Med. 2021 Jun 21:S2213-2600(21)00084-9. doi: 10.1016/S2213-2600(21)00084-9.

About ORPATHYS®(savolitinib)

ORPATHYS® is an oral, potent, and highly selective MET tyrosine kinase inhibitor ("TKI") that has demonstrated clinical activity in advanced solid tumors. It blocks atypical activation of the MET receptor tyrosine kinase pathway that occurs because of mutations (such as exon 14 skipping alterations or other point mutations) or gene amplification.

ORPATHYS® is marketed in China for the treatment of patients with NSCLC with MET exon 14 skipping alterations who have progressed following prior systemic therapy or are unable to receive chemotherapy. In 2011, following its discovery and initial development by HUTCHMED, AstraZeneca and HUTCHMED entered a global licensing agreement to jointly develop and commercialize savolitinib. Joint development in China is led by HUTCHMED, while AstraZeneca leads development outside of China. HUTCHMED is responsible for the marketing authorization, manufacturing and

supply of savolitinib in China. AstraZeneca is responsible for the commercialization of savolitinib in China and worldwide. Sales of savolitinib are recognized by AstraZeneca.

About 8-gene Lung Cancer Assay (Tissue) and One-Step Seq Method

The 8-gene Lung Cancer Assay (Tissue) 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. This assay has been approved by the NMPA as an IVD assay to identify EGFR 19 del and L858R-positive, metastatic NSCLC patients who are candidates for gefitinib and icotinib tablets, T790M-positive NSCLC patients who are candidates for osimertinib tablets, and ALK fusion gene-positive NSCLC patients who are candidates for crizotinib tablets.

8-gene Lung Cancer Assay (Tissue) was developed 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.

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.

About HUTCHMED

HUTCHMED (Nasdaq/AIM:HCM; HKEX:13) is an innovative, commercial-stage, biopharmaceutical company. It is committed to the discovery and global development and commercialization of targeted therapies and immunotherapies for the treatment of cancer and immunological diseases. It has more than 4,600 personnel across all its companies, at the center of which is a team of about 1,500 in oncology/immunology. Since inception it has advanced 12 cancer drug candidates from in-house discovery into clinical studies around the world, with its first three oncology drugs now approved and marketed in China. For more information, please visit: https://www.hutch-med.com/ or follow the company on LinkedIn.

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, such as our expectation on further increase of Lung 8's penetration into China's top hospitals, 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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