Genetron Health and CStone Pharmaceuticals Announce Launch of Clinical Trial in China for Companion Diagnostic Test in Development for Avapritinib

September 25, 2020

BEIJING and SUZHOU, China, Sept. 25, 2020 (GLOBE NEWSWIRE) -- Genetron Holdings Limited (“Genetron Health”, 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, and its strategic partner CStone Pharmaceuticals (“CStone”, HKEX: 2616) today announced the launch of a multi-center clinical trial in China for the joint development of a companion diagnostic (CDx) test for avapritinib. This represents a key milestone in the companies’ collaboration. Avapritinib is a kinase inhibitor discovered by CStone’s partner Blueprint Medicines.

Genetron Health and CStone are jointly developing a CDx kit to detect the D842V mutation in the human platelet-derived growth factor receptor alpha (PDGFRA) gene using a polymerase chain reaction (PCR)-based method. The CDx test kit utilizes a real-time PCR fluorescent probe, combined with specific primers, Taqman probes, and highly specific Taq enzymes, to detect the mutation with high specificity and sensitivity in DNA samples. The test has been validated by the testing center of the National Medical Products Administration (NMPA) and is now being used in this multi-center clinical trial in China.

CStone submitted New Drug Applications for avapritinib in PDGFRA exon 18 mutant gastrointestinal stromal tumors (GIST) to regulatory agencies in Taiwan and Mainland China in March and April 2020, respectively. The Chinese regulatory application has been accepted by the Center for Drug Evaluation (CDE) of NMPA for priority review. Data from the Phase I/II bridging study of avapritinib presented at the Chinese Society of Clinical Oncology (CSCO) annual meeting in 2020 showed that avapritinib was generally well tolerated in Chinese patients, with a safety profile that is consistent with previously published results in global studies. Preliminary results demonstrated the robust clinical activity of avapritinib in Chinese patients with GIST harboring the PDGFRA D842V mutation. Among the eight evaluable patients with PDGFRA D842V mutant GIST who received 300 mg QD doses of avapritinib, all of the patients had evidence of tumor regression in target lesions, and five patients achieved a partial response. The overall response rate (ORR) was 62.5%. The other three patients had stable disease.

With the rapid development of targeted therapy, immunotherapy, and other innovative anti-cancer drugs, companion diagnostic tests have become an integral part of precision therapy in oncology. Pending avapritinib’s regulatory approval in China, the collaboration between Genetron Health and CStone is designed to enhance the commercial potential, maximize benefits to patients, and promote the development of precision medicine for GIST.

About Avapritinib
Avapritinib is a kinase inhibitor approved by the U.S. Food and Drug Administration (FDA) under the brand name AYVAKIT™ for the treatment of adults with unresectable or metastatic GIST harboring a PDGFRA exon 18 mutation, including PDGFRA D842V mutations. Previously, the U.S. FDA granted Breakthrough Therapy Designation to avapritinib for the treatment of adult patients with unresectable or metastatic GIST harboring the PDGFRA D842V mutation.

Avapritinib is not approved for the treatment of any other indication in the U.S. by the FDA or for any indication in any other jurisdiction by any other health authority.

Blueprint Medicines is developing avapritinib globally for patients with advanced and indolent systemic mastocytosis (SM). The FDA granted breakthrough therapy designation to avapritinib for the treatment of advanced SM, including the subtypes of aggressive SM, SM with an associated hematologic neoplasm and mast cell leukemia.

CStone and Blueprint Medicines have an exclusive collaboration and license agreement for the development and commercialization of avapritinib and certain other drug candidates in Mainland China, Hong Kong, Macau, and Taiwan. Blueprint Medicines retains development and commercial rights for avapritinib in the rest of the world.

CStone submitted an NDA for avapritinib to the TFDA and the China NMPA in March and April 2020, respectively, for the treatment of adult patients with unresectable or metastatic GIST harboring a PDGFRA exon 18 mutation. In July 2020, avapritinib received priority review designation from the China NMPA.

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 CStone Pharmaceuticals
CStone Pharmaceuticals (HKEX: 2616) is a biopharmaceutical company focused on developing and commercializing innovative immuno-oncology and precision medicines to address the unmet medical needs of cancer patients in China and worldwide. Established in 2015, CStone has assembled a world-class management team with extensive experience in innovative drug development, clinical research, and commercialization. The company has built an oncology-focused pipeline of 15 drug candidates with a strategic emphasis on immuno-oncology combination therapies. Currently, 5 late-stage candidates are at pivotal trials. With an experienced team, a rich pipeline, a robust clinical development-driven business model and

substantial funding, CStone's vision is to become globally recognized as a leading Chinese biopharmaceutical company by bringing innovative oncology therapies to cancer patients worldwide.

For more information, please visit the www.cstonepharma.com

Safe Harbor Statement
This press release contains forward-looking statements within the meaning of federal securities laws, including [results of the Phase I/II bridging study of avapritinib conducted by CStone and] collaboration with CStone for the joint development of a CDx test for avapritinib, which involve risks and uncertainties that could cause the actual results to differ materially from the anticipated results and expectations expressed in these 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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