



ANSWERS FOR CANCER

Genetron Health Provides Update on HCCscreen™ for Liver Cancer Early Screening in China

November 27, 2020

HCCscreen™ was selected by the National Cancer Center and the Wuxi municipal government for use in the “Liver Cancer Early Screening Comprehensive Prevention and Control Project”, a public health initiative

Establishes joint venture with Wuxi municipal government; Expects the commercialization and revenues of HCCscreen™ to accelerate in China

Project facilitates real-world data generation, representing an important step for early screening development and broader commercialization path

BEIJING--(BUSINESS WIRE)--Nov. 27, 2020-- 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 provided an update for HCCscreen™, its blood-based early screening test for hepatocellular carcinoma (“HCC”), in China.

Led by the Wuxi municipal government (“Wuxi”) and administered by the National Cancer Center (NCC) in China, the “Liver Cancer Early Screening Comprehensive Prevention and Control Project” is a public health initiative (the “Project”). The goal of the Project is to increase the awareness of liver cancer early screening, and to become a pilot city model in China. For the Project, Wuxi has selected HCCscreen™ for local residents who are high-risk individuals for HCC, and is committed to administering 150,000 tests over a period of three years. Wuxi had entered into a small-scale collaboration agreement with Genetron Health in 2019, and the Project represents an expanded collaboration between the parties. Wuxi is a city in the southern part of Jiangsu Province in eastern China with a population of over six million people, and has emerged as a biopharma innovation hub in recent years.

Separately, Genetron Health has formed a new operating center through a joint venture agreement with Wuxi, in which the parties will closely collaborate on advancing the liver cancer early screening market in China, through the adoption of HCCscreen™. Under this joint venture agreement, both parties will contribute capital, and Genetron Health will own 90% of the joint venture. In addition to the commitment of using HCCscreen™ for its residents, Wuxi will also provide Genetron Health with other supportive measures including rental, R&D subsidies and tax benefits.

“We are thrilled about this strategic partnership with Wuxi. It represents a major milestone for HCCscreen™ as it will be broadly used in a real-world setting, reflecting its clinical value that both the NCC and Wuxi recognized. Wuxi’s investment and other supportive measures also highlight its commitment to advancing the liver cancer early screening in China,” commented Sizhen Wang, Genetron Health’s co-founder and CEO. “This partnership provides Genetron Health with near term revenue opportunities, as well as a cost-effective structure to build another world-class lab, manufacturing facility and an operating center for future developments. Beyond the financial benefits, the strategic value from this partnership is tremendous. It enables large-scale, real-world adoption of HCCscreen™, representing an important step for our early screening product development, as well as potentially serving as a pilot model as we navigate the broader commercialization and reimbursement roadmaps in the future. Overall, we expect this initiative to ultimately help drive faster adoption of early cancer detection products in China.”

About HCCscreen™ and Liver Cancer

In September 2020, Genetron Health received the U.S. Food and Drug Administration (“FDA”)’s Breakthrough Device designation for HCCscreen™, and the product has been commercialized recently as a lab developed test (“LDT”) in China.

Globally, liver cancer is the fourth most common cause of cancer-related death and the sixth in terms of incidence¹. China represents the largest market, accounting for almost half of the global incidences. New incidence in China was estimated to be around 393,000 per year, with 369,000 deaths². Market data by Frost and Sullivan estimated that as of 2019, among the 120 million high risk liver cancer population in China, around 74 million were HBV carriers.

Powered by Genetron Health’s innovative and proprietary Mutation Capsule™ technology, which enables detection of multiple methylation alterations in parallel with mutations in cell-free DNA from peripheral blood specimens, HCCscreen™ is currently being tested in its ongoing prospective study with 4,500 HBsAg+ individuals in HCC. As of the date of this announcement, 2,000 patients have already completed the study, and preliminary data from 297 patients at one center has demonstrated over 92% sensitivity, 93% specificity, compared to 67% and 99%, respectively in the ultrasound plus alpha-fetoprotein (AFP) arm. HCCscreen™ also achieved a 35% positive predictive value and 99.6% negative predictive value. Furthermore, stratifying by tumor sizes, of the 12 patients identified with HCC in the preliminary dataset, 10 patients had tumor sizes of less than 5 centimeters. Of these, seven patients had tumor sizes of less than 3 centimeters, and HCCscreen™ successfully detected them all, indicating its ability in detecting early-stage HCC.

In August 2020, Genetron Health announced its participation in the launch of a major national research project for early screening of lung and digestive system cancers led by China’s Ministry of Science and Technology. The project is designed to include a multi-center, prospective cohort study in lung cancer of 120,000 high-risk individuals in 20 provinces, as well as a cohort study in digestive system cancer of more than 100,000 patients in urban areas in China. Genetron Health is the only company in China involved in national key research and development projects for liver, lung and digestive cancer early screening.

References:

1. Villanueva, A. Hepatocellular Carcinoma. N. Engl. J. Med. 2019, 380, 1450–1462.
2. Globocan 2018. <https://gco.iarc.fr/today/data/factsheets/populations/160-china-fact-sheets.pdf>. Information on this website is not incorporated into this update and should not be considered part of this update. We have included any website as an inactive textual reference only.

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 within the meaning of federal securities laws, including statements regarding the prospects of the joint venture arrangement and plans for commercialization and expectation of revenues of HCCscreen™, 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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Investor Relations Contacts

US:

Hoki Luk

Head of Investor Relations

Email: hoki.luk@genetronhealth.com

Phone: +1 (408) 891-9255

Stephanie Carrington

Westwicke, an ICR Company

Email: Stephanie.Carrington@westwicke.com

Phone: +1 (646) 277-1282

Asia:

Bill Zima

ICR, Inc.

Email: bill.zima@icrinc.com

GenetronIR@icrinc.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

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