

### Genetron Health Releases New Data Results of HCCscreen™ for Liver Cancer Early Screening in China

March 24, 2021

*HCCscreen™ achieved 88% sensitivity and 93% specificity, compared with 71% and 95%, respectively, by ultrasound plus AFP.*

*In early-stage patients, the sensitivities of HCCscreen™ are 85% (tumor size of <3cm) and 96% (3-5 cm).*

*The Company plans to initiate an NMPA registrational trial in China in Q2 2021.*

*Management team will discuss the data at the upcoming March 25, 2021 earnings conference call.*

BEIJING--(BUSINESS WIRE)--Mar. 24, 2021-- Genetron Holdings Limited ("Genetron Health" or the "Company", NASDAQ:GTH), a leading precision oncology platform company in China that specializes in molecular profiling tests, early cancer screening products and companion diagnostics development, today presented new data and results for HCCscreen™, a blood-based early screening test for hepatocellular carcinoma ("HCC").

This multi-center prospective study, named the "HCCscreen™ Investigational Study" (HIT), is a collaboration between Genetron Health and the National Cancer Center China that started in 2019. Among a total of 1,615 HBsAg+ individuals that completed the follow-up phase by February 2021, the primary outcome showed that HCCscreen™ achieved 88% sensitivity and 93% specificity, compared with 71% sensitivity and 95% specificity, respectively, by ultrasound plus alpha-fetoprotein (AFP) combined. HCCscreen™ also achieved 40.9% positive predictive value (PPV) and 99.3% negative predictive value (NPV). The study results are summarized in the following tables:

Table 1. HIT Results: Genetron HCCscreen™ Final Analysis (N=1615)

HCCscreen™ Test	HCC	Non-HCC	Total
Test - Positive	76	110	186
Test - Negative	10	1,419	1,429
Total	86	1,529	1,615
Sensitivity (95% CI)	88% (80%, 94%)		
Specificity (95% CI)	93% (91%, 94%)		

Table 2. HIT Results: Ultrasound + AFP Final Analysis (N=1615)

Ultrasound + AFP	HCC	Non-HCC	Total
Test - Positive	61	83	144
Test - Negative	25	1,446	1471
Total	86	1,529	1615
Sensitivity (95% CI)	71% (60%, 80%)		
Specificity (95% CI)	95% (93%, 96%)		

Furthermore, stratified by tumor size, 49% (28/57) of the cases identified by HCCscreen™ were in early stage, i.e. <3cm. These patients are expected to have much better prognosis than advanced stage ones. Additionally, HCCscreen™ achieved sensitivities of 85% for tumor sizes of <3cm, 96% for 3-5cm, and 88% for >5cm. The results are summarized in the following table:

Table 3. HIT Results: Genetron HCCscreen™ Sensitivities by Tumor Size

HCCscreen™ Test	Tumor Size (N=64)			Total
	<3cm	3-5cm	>5cm	
Test Positive	28	22	7	57
Test Negative	5	1	1	7
Total	33	23	8	64
Sensitivity	85%	96%	88%	

Previously, Genetron Health reported preliminary analysis results from the first 297 patients enrolled in the study. Compared with the preliminary results, the confidence interval of sensitivity had improved from 62%-100% to 80%-94%, and the confidence interval of specificity had improved from 89%-96% to 91%-94%. The preliminary study results are summarized in the following table:

Table 4. HIT Results: Genetron HCCscreen™ Preliminary Data (N=297)

HCCscreen™ Test	HCC	Non-HCC	Total
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Test - Positive	11	20	31
Test - Negative	1	265	266
Total	12	285	297
Sensitivity (95% CI)	92% (62%, 100%)		
Specificity (95% CI)			93% (89%, 96%)

"We are very pleased with the new HCCscreen™ data from this large, prospective cohort study, which showed overall better sensitivity data, and comparable specificity data versus the standard of care. These additional validation updates gave us more confidence about our assay's performance, and we will move forward to initiate an NMPA registrational study in the second quarter of this year," said Mr. Sizhen Wang, co-founder and CEO of Genetron Health. "Overall, HCCscreen™ continues to be a leading liquid-biopsy early detection assay in hepatocellular carcinoma. We are delighted with our clinical and commercial progress to bring this product to more patients, and address an unmet, significant medical need 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 incidence<sup>1</sup>. 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 deaths<sup>2</sup>. 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.

HCCscreen™ is 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.

#### 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](http://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 and prospectus of and plans for commercializing HCCscreen™ in China, 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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