Activated University of Michigan as The Second Site for Clinical Trial in Severe Esophageal Disease

PR Newswire

HOLLISTON, Mass. , Aug. 28, 2023 /PRNewswire/ -- Harvard Apparatus Regenerative Technology, Inc. (OTCQB: HRGN) ("Harvard Apparatus Regenerative Technology" or the "Company"), a clinical-stage biotechnology company developing the technology to regenerate organs inside the body to treat severe diseases, today announced that it officially activated the second site with University of Michigan for its clinical trial as to severe esophageal disease, being its first clinical trial in the United States .

"Our primary focus continues to be accelerating the clinical development of our CEI platform as a potential treatment alternative for unmet needs. The entire HRGN team remains highly excited by the pace at which our clinical trial is being executed in the study," commented Jerry He , HRGN's Chief Executive Officer.

"This activation of the second clinical site demonstrates the ability of HRGN's commitment to substantially accelerate the clinical development timelines for the company. We have worked diligently to recruit patients for the trial and are grateful for the tremendous support from our partners and the clinical staff and remain dedicated to driving patient enrollment as quickly and efficiently as possible," commented Shunfu (Sean) Hu , VP of Business Development and Operations.

About Harvard Apparatus Regenerative Technology, Inc.

We are a clinical-stage biotechnology company developing regenerative-medicine treatments for disorders of the gastro-intestinal system and other organs resulting from cancer, trauma or birth defects. Our technology is based on our proprietary cell-therapy platform that uses a patient's own stem cells to regenerate and restore function to damaged organs. We believe that our technology represents a next-generation solution for restoring organ function because it allows the patient to regenerate their own organ, thus eliminating the need for human donor or animal transplants, the sacrifice of another of the patient's own organs or permanent artificial implants.

We conducted the world's first successful regeneration of the esophagus in a patient with esophageal cancer in August 2017 . This surgery was performed by Dr. Dennis Wigle , Chair of Thoracic Surgery at the Mayo Clinic. The results were published in the Journal of Thoracic Oncology Clinical and Research Reports in August 2021 . The procedure demonstrated that our technology was able to successfully regenerate esophageal tissue, including the mucosal lining, to restore the integrity, continuity and functionality of the esophageal tube.

HRGN has 13 issued U.S. patents, 2 issued in China , 1 issued in Japan , 2 issued in Europe , 2 U.S. orphan-drug designations which can provide seven years of market exclusivity in the US market after market approval from the FDA and 1 EMA orphan drug designation, which can provide ten years of market exclusivity in the European market after market approval from the EMA.

For more information, please visit www.hregen.com and connect with the Company on LinkedIn .

Forward-Looking Statements

Some of the statements in this press release are "forward-looking" and are made pursuant to the safe harbor provision of the Private Securities Litigation Reform Act of 1995. These "forward-looking" statements in this press release include, but are not limited to, statements relating to the capabilities and performance of our products and product candidates; development expectations and regulatory approval of any of the Company's products, by the U.S. Food and Drug Administration, the European Medicines Agency or otherwise, which expectations or approvals may not be achieved or obtained on a timely basis or at all; and success with respect to any collaborations, clinical trials and other development and commercialization efforts of the Company's products, which such success may not be achieved or obtained on a timely basis or at all. These statements involve risks and uncertainties that may cause results to differ materially from the statements set forth in this press release, including, among other things, the Company's inability to obtain needed funds in the immediate future; the Company's ability to obtain and maintain regulatory approval for its products; plus other factors described under the heading "Item 1A. Risk Factors" in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2022 or described in the Company's other public filings. The Company's results may also be affected by factors of which the Company is not currently aware. The forward-looking statements in this press release speak only as of the date of this press release. The Company expressly disclaims any obligation or undertaking to release publicly any updates or revisions to such statements to reflect any change in its expectations with regard thereto or any changes in the events, conditions or circumstances on which any such statement is based.

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