Approval of an Orphan Disease Application for its lead product, the Cellspan Esophageal Implant by the European Medicines Agency

Holliston, MA – August 21, 2023 – 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 the Approval of an Orphan Disease Application for its lead product, the Cellspan Esophageal Implant by the European Medicines Agency (EMA). The EMA is the centralized regulatory agency for the review and approval of new medicines in the European Union as well as Iceland, Norway and Liechtenstein.

The Orphan Disease Designation (ODD) was approved to treat Esophageal Atresia, a congenital disorder where children are born with an incomplete, underdeveloped esophagus. The World-Wide incidence of Esophageal Atresia is estimated to be 1/2500 to 1/4000 live births.The designation provides Harvard Apparatus Regenerative Technology with exclusive marketing rights, as well as additional benefits related to clinical protocol development and Scientific Advice.

Specifically, access to the Centralized Authorization procedure allows companies to make a single application to the European Medicines Agency, resulting in a single opinion and a single decision from the European Commission, valid in all EU Member States. Sponsor's may also have access via orphan designation to *conditional approval*, which is conducted under the centralized procedure.

Authorized orphan medicines benefit from **ten years of protection** from market competition with similar medicines with similar indications once they are approved. This period of protection is **extended by two years** for medicines that also have complied with an agreed pediatric investigation plan granted at the time of review of the orphan medicine designation.

Although the Agency does not offer research grants for sponsors of orphan medicines, funding opportunities are available from the European Commission as well as other sources, including *Horizon Europe* and the *E-Rare ERA-NET* program for rare diseases.

Mr Jerry He, CEO, commented, "the ODD will expedite our efforts to bring Cellspan Esophageal Implant to the European market".

Dr. William Fodor, CSO, commented, “the approval of the ODD application further supports our position as a leading developer of tissue engineered organ replacement products designed to replace, restore and regenerate new tissues in congenital organ deficiencies, as well as in tubular organs that are damaged by disease or injury.”

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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