Harvard Apparatus Regenerative Technology No Longer Supporting Studies in Russia; Will Continue Focus on Preclinical Processes in the U.S. and EU

HOLLISTON, Mass.--(BUSINESS WIRE)--Harvard Apparatus Regenerative Technology, Inc. (Nasdaq: HART), or HART, a clinical stage biotechnology company developing regenerated organs for transplant, initially focused on the trachea announced that it will no longer be providing its HART-Trachea product for future transplant procedures performed at Krasnodar, Russia as part of the ongoing airway transplant studies there. HART will continue to focus primarily on completing preclinical work necessary to initiate clinical trials for its HART-Trachea product in the EU and U.S. It has made recent progress in the U.S. and EU, including the granting of orphan designation by the U.S. Food and Drug Administration (FDA) and a productive meeting with the Medicines and Healthcare Products Regulatory Agency of the U.K. (MHRA, the equivalent of the FDA in the U.K.). HART anticipates that during 2015 it will file its Investigational New Drug application to initiate a U.S. clinical trial and a Clinical Trial Authorization application to initiate an EU clinical trial.

About Harvard Apparatus Regenerative Technology

Harvard Apparatus Regenerative Technology makes regenerated organs for transplant. Our first product, the HART-Trachea, is intended to replace or repair a trachea that has been severely damaged by either physical trauma or trachea cancer. Our trachea scaffold technology has been used in six human trachea transplants to date approved under compassionate use exemptions, but none of our products are yet approved by a government regulatory authority for marketing. On November 1, 2013, HART was spun-off from Harvard Bioscience. The trademark “Harvard Apparatus” is used under a sublicense agreement with Harvard Bioscience, who has licensed the right to use such trademark from Harvard University.

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 regulatory filings and approval pertaining to the HART-Trachea or any other HART products, by the FDA, MHRA, European Medicines Agency, or otherwise, which such filings or approvals may not be made or obtained on a timely basis or at all, and success with respect to any clinical trials and other regulatory approval efforts, commercialization efforts and marketing approvals of HART’s products as well as the success thereof, including our HART-Trachea product. 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, factors described under the heading “Item 1A. Risk Factors” in our Annual Report on Form 10-K for the fiscal year ended December 31, 2013 or described in our other public filings. Our results may also be affected by factors of which we are not currently aware. The forward-looking statements in this press release speak only as of the date of this press release. Harvard Apparatus Regenerative Technology 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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