

# Five-Year Follow-Up of World's First Regenerated Trachea Transplant Published in The Lancet

## **Transplant Patient Enjoys Good Quality of Life With No Complications**

HOLLISTON, Mass., Oct. 23, 2013 (GLOBE NEWSWIRE) -- Harvard Bioscience, Inc. (Nasdaq:HBIO) and Harvard Apparatus Regenerative Technology (Nasdaq:HARTV) jointly announce that five years after a 30-year-old woman was implanted with the world's first tissue-engineered trachea grown in a bioreactor she lives complication-free, according to an article published October 23 in *The Lancet*.

According to the article, titled "The first tissue-engineered airway transplantation: 5-year follow-up results," the patient, Claudia Castillo, is living normally without any complications or rejection of the implanted airway. In 2008, after part of her own trachea collapsed due to complications from tuberculosis, Castillo underwent surgery led by Professor Paolo Macchiarini and his research team at the Hospital Clinic of Barcelona in Spain.

The replacement tissue-engineered trachea was produced by removing the cells from a human donor trachea, which was then placed inside the bioreactor, where it was recellularized with cartilage cells derived from Castillo's own stem cells and epithelial cells taken from a healthy part of her trachea. Castillo was discharged from the hospital on the 10th postoperative day, and after four months the graft had a normal appearance and properties. This world's first transplant of a regenerated trachea was published in *The Lancet* in December 2008.

In today's *Lancet* article, Professor Macchiarini and colleagues write that regular testing of lung function, immunological response to the transplant, and other key indicators reveal that Castillo has retained good lung function five years after the surgery and has not experienced any immunological complications.

In the article, Professor Macchiarini and colleagues conclude, "Our findings provide initial evidence that a tissue-engineering strategy, including decellularization of a human trachea, autologous epithelial and stem cell culture and differentiation, and cell-scaffold seeding using a bioreactor, are safe and promising."

David Green, President of Harvard Bioscience, and CEO of Harvard Apparatus Regenerative Technology (HART), said, "The positive results reported in *The Lancet* bolster our belief that tissue-engineered transplants, made possible in part by our bioreactor, are safe and effective in the long-term. Although further work must be done before this stem cell-based tissue engineering technology can be translated into routine clinical practice, we are greatly encouraged by these results. They bode well not only for implants involving decellularized human donor organs, but, because the cell-seeding and implant procedures are almost identical, also for the long-term success of organs grown on synthetic scaffolds in our bioreactors—an endeavor on which we have collaborated with Professor Macchiarini and his team in recent years."

Mr. Green continued, "Following this pioneering surgery, Harvard Bioscience licensed the bioreactor technology, from which we developed our InBreath <sup>™</sup> Bioreactor, which has been used in all nine subsequent regenerated trachea transplant surgeries conducted by Prof. Macchiarini. Since 2011, we have collaborated with him to develop fully synthetic scaffolds. Synthetic scaffolds are preferable to donor scaffolds because the number of donor organs is very limited and the donor scaffold weakened over time in the patient's body. Our current product, the InBreath <sup>™</sup> Airway Transplant System, which utilizes the InBreath <sup>™</sup> Bioreactor and the InBreath <sup>™</sup> Scaffold, has been used in four successful regenerated human airway transplantations."

Harvard Bioscience recently completed the acquisition of all patent rights to synthetic scaffold-based trachea regeneration owned by Professor Macchiarini. Additionally, as previously announced, Harvard Bioscience will spin-off Harvard Apparatus Regenerative Technology on November 1, 2013. Thereafter, HART will be an independent publicly traded biotechnology company focused on developing regenerative medicine therapies, initially for trachea cancer. HART will trade on the NASDAQ market under the ticker symbol HART.

To read the *Lancet* article, please <u>click here</u>, or paste this URL into your browser: thelancet.com/journals/lancet/article/PIIS0140-6736(13)62033-4/abstract

### About Harvard Apparatus Regenerative Technology

Harvard Apparatus Regenerative Technology is a clinical stage regenerative medicine company developing life-saving medical products. HART's first product, the InBreath <sup>™</sup> Airway Transplant System, is intended to repair a trachea that has been severely damaged by either trachea cancer or physical trauma. None of HART's products are yet approved by a government regulatory authority for marketing. Additionally, as previously announced, Harvard Bioscience will spin-off Harvard Apparatus Regenerative Technology on November 1, 2013. HART has filed a trademark application with respect to the InBreath trademark. The trademark "Harvard Apparatus" is used by Harvard Bioscience and HART under a license agreement with Harvard University. For more information, please visit our website at <a href="http://www.harvardapparatusregen.com/index.php/">http://www.harvardapparatusregen.com/index.php/</a>

### **About Harvard Bioscience**

Harvard Bioscience ("HBIO") is a global developer, manufacturer and marketer of a broad range of specialized products, primarily apparatus and scientific instruments, used to advance life science research and regenerative medicine. Our products are sold to thousands of researchers in over 100 countries primarily through our 850 page catalog (and various other specialty catalogs), our website, through distributors, including GE Healthcare, Thermo Fisher Scientific and VWR, and via our field sales organization. HBIO has sales and manufacturing operations in the United States, the United Kingdom, Germany, Sweden and Spain with additional facilities in France and Canada. For more information, please visit our website at <u>www.harvardbioscience.com</u>.

The Harvard Bioscience, Inc. logo is available at

http://www.globenewswire.com/newsroom/prs/?pkgid=6426

#### **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 include statements relating to, among other things, the intention to consummate the spin-off of Harvard Apparatus Regenerative Technology, the availability of a market for the HART securities, the success of surgeries using the products of Harvard Bioscience or HART, and any commercialization efforts and marketing approvals of Harvard Bioscience or HART's products as well as the success thereof. These statements involve risks and uncertainties, including among other things, market conditions that may cause results to differ materially from the statements set forth in this press release. The forward-looking statements in this press release speak only as of the date of this press release. Harvard Bioscience 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.

For investor inquiries, please call (508) 893-8066. Press releases may be found on our web site.

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