# Biostage Successfully Regenerates Esophagus in Groundbreaking Pre-Clinical Work with Mayo Clinic; Data Provides 'Proof of Concept' to Seek FDA Approval for Clinical Trials

**Biostage Hosts Conference Call Today at 9:00 a.m. ET to Review Research Findings and Their Significance for Advancing Regulatory and Clinical Goals.**

HOLLISTON, Mass., May 12, 2016 /PRNewswire/ -- Biostage, Inc. (Nasdaq: BSTG), a biotechnology company developing bioengineered organ implants to treat cancers and other life-threatening conditions of the esophagus, bronchus and trachea today announced significant, pre-clinical data, including the complete regeneration of a segment of the esophagus, from its collaborative large-animal study of its Cellspan™ organ implants with Mayo Clinic. Biostage will review this research in a conference call today at 9:00 am ET (details below).

**Groundbreaking Results:**
The study has clearly demonstrated in a predictive large-animal model the ability of Biostage Cellspan organ implants to successfully stimulate the regeneration of sections of esophagus that had been surgically removed for the study. Cellspan esophageal implants, consisting of a proprietary biocompatible synthetic scaffold seeded with the recipient animal's own stem cells, were surgically implanted in place of the esophagus section that had been removed.

Study animals were returned to a solid diet two weeks after implantation surgery. The scaffolds, which are intended to be in place only temporarily, were later retrieved via the animal's mouth in a non-surgical endoscopic procedure. After 2.5 months, a complete epithelium and other specialized esophagus tissue layers were fully regenerated. Animals in the study demonstrated weight gain and appear healthy and free of any significant side effects, including a few that are now more than 90 days post implantation, and are receiving no specialized care.

Dennis Wigle, M.D., Ph.D., Associate Professor of Surgery and Chair of Thoracic Surgery at Mayo Clinic, and Saverio La Francesca, M.D., Chief Medical Officer of Biostage, are principal investigators for the study. The investigators intend to publish images and details of the study in a peer-reviewed scientific publication.

Saverio La Francesca, M.D., Chief Medical Officer of Biostage, commented, "Beyond the unparalleled evidence of tissue regeneration, we are also very encouraged that there has been no evidence of leakage or infection at the surgery sites in any of the animals studied so far. Such issues pose regular and life-threatening dangers for esophageal cancer patients surgically treated with the existing standards of care. These results represent a dramatic step forward in our quest to bring new solutions to patients with life-threatening conditions."

**Cellframe™ (Animation-Link) Represents Potential Breakthrough in Regenerative Medicine:**
Developed over the past two years, Biostage's Cellframe technology utilizes what the Company believes to be an entirely new approach to creating organ implants, including new materials, new protocols and a different mechanism of action, that are enabling these groundbreaking results. Prior organ implant technologies sought to incorporate the scaffold into the body wherein the surrounding native tissue would grow into, or incorporate, the scaffold. However this approach was challenged by the body's immune response, creating significant complications.

In Biostage's new Cellframe approach, the scaffold is designed to serve as a temporary host structure that delivers the necessary cells in a suitable form and manner to support regeneration. Cellspan implants utilize a biocompatible tubular structure or 'scaffold' to guide the formation of new tissue. Prior to implantation, stem cells from each subject are 'seeded' on the scaffold to stimulate tissue regeneration as well as to help reduce any potential inflammatory or rejection response. Once initial regeneration activity has taken place, the scaffold is retrieved, enabling the inner surface to continue the regeneration process from both ends.

Jim McGorry, Biostage CEO, commented, "We could not have asked for a more encouraging outcome from these large-animal studies. The data suggests our Cellspan esophageal implant could be a break-through alternative to the current surgical procedures used to address esophageal cancer.

"We view our research results as a watershed event for Biostage that strongly validates our science, corporate strategy and goals, while also providing hope for cancer patients facing life-altering treatment options. In support of our mission we have made important enhancements to our team over the last few months in the areas of regulatory affairs, quality and operations, and we have also expanded our Board and launched a Scientific Advisory Board. We feel these actions strongly position Biostage to pursue our regulatory and clinical goals."

Biostage believes it now possesses sufficient data to initiate Good Laboratory Practice (GLP) studies to demonstrate that its technology, personnel, systems and practices are sufficient for advancing into clinical trials. GLP studies are required to advance to an Investigational New Drug (IND) application with the U.S. FDA, which would seek approval to initiate clinical trials for Biostage Cellspan esophageal implants in humans. Biostage currently expects to complete its IND filing by year-end 2016.

**Conference Call Information:**

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| **Date/Time:** | Today, Thursday, May 12th at 9:00 am ET |
| **Call Dial In #:** | 877-407-8293 U.S. or 201-689-8349 Int'l |
| **Live Webcast/Replay:** | biostage.com/events-and-presentations |
| **Audio Replay:** | 877-660-6853 U.S. or 201-612-7415 Int'l - Access ID #13636819 |

**About Biostage, Inc.:** www.biostage.com
Biostage is a biotechnology company developing bioengineered organ implants utilizing the company's new Cellframe™ technology which combines a proprietary biocompatible scaffold with a patient's own stem cells to create Cellspan™ organ implants. Cellspan implants are being developed to treat life-threatening conditions of the esophagus, bronchus and trachea with the hope of dramatically improving the treatment paradigm for patients. Based on its preclinical data, Biostage has selected life-threatening conditions of the esophagus as the initial clinical application of its technology.

Cellspan implants are currently being advanced and tested in a collaborative preclinical study. This testing is intended to expand the base of preclinical data in support of Biostage's goal of filing an Investigational New Drug (IND) application with the U.S. FDA in late 2016. The IND will seek approval to initiate clinical trials for its esophageal implants in humans.

**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 development expectations and regulatory approval of any of our products, including those utilizing our Cellframe technology, by the FDA, EMA, MHRA or otherwise, which expectations or approvals may not be achieved or obtained on a timely

basis or at all; or success with respect to any collaborations, clinical trials and other development and commercialization efforts of our products, including those utilizing our Cellframe technology, 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, our ability to obtain and maintain regulatory approval for our products; plus other factors described under the heading "Item 1A. Risk Factors" in our Annual Report on Form 10-K for the fiscal year ended December 31, 2015 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. Biostage 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.

**Twitter: BiostageIR**
**StockTwits: BiostageIR**


**Media/Investor Relations Contact:**

| | |
|---|---|
| Tom McNaughton | David Collins, Bill Jones, Helen Sun |
| Chief Financial Officer | Catalyst Global LLC |
| 774-233-7321 | 212-924-9800 w; 917 734-0339 m |
| | bstg@catalyst-ir.com |


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