

Biostage Presents Positive Preclinical Data of Cellspan Esophageal Implant at Society For Biomaterials 2017 Annual Meeting and Exposition

- Preclinical results demonstrate potential of Company's Cellspan Esophageal Implant to facilitate esophageal regeneration after resection -

HOLLISTON, Mass., April 6, 2017 /PRNewswire/ -- [Biostage, Inc.](#) (Nasdaq: BSTG), ("Biostage" or the "Company"), a biotechnology company developing bioengineered organ implants to treat life-threatening conditions of the esophagus, bronchus and trachea, today presented preclinical data of its Cellspan™ Esophageal Implant at the [Society for Biomaterials 2017 Annual Meeting and Exposition](#), being held April 5-8, 2017 in Minneapolis, MN.

Sherif Soliman, PhD, Head of Biostage's Material Science Laboratory, presented the Company's preclinical data in an abstract entitled, "*Cell-Seeded Synthetic Scaffold for Esophageal Regeneration*," in an oral presentation as part of the *Biomaterials Technology in Industry* session, on April 5, 2017. The Company's abstract will also be a part of poster presentations (poster number 845) being held on Thursday, April 6 and Friday, April 7, 2017.



The preclinical study was designed to evaluate the Company's Cellspan Esophageal Implant as an alternative conduit for patients with esophageal diseases that require resection of the damaged portion. In the preclinical model, autologous adipose-derived mesenchymal stem cells were isolated, expanded and seeded onto a tubular synthetic scaffold created with electrospun polycarbonate based polyurethane. Scaffolds were then incubated in a disposable bioreactor for 7 days to obtain an autologous combination construct, and were then implanted in large animals after a full circumferential resection of the esophagus.

In vitro data showed that the Cellspan implant dependably carried metabolically active cells that released bioactive molecules involved in the mesenchymal cells paracrine function. *In vivo* studies resulted in tissue growth that led to the reconstitution of the continuity and integrity of the esophageal tube after circumferential full thickness surgical resection. Furthermore, full mucosal regeneration on the inner lumen was observed within a span of 3 months post-implantation.

[Saverio La Francesca, MD, President and Chief Medical Officer](#) of Biostage, stated, "The overall results further demonstrate the potential of our Cellspan Esophageal Implant and its feasibility to facilitate the regeneration of full circumferential sections after esophageal resection, as it would be clinically required for esophageal replacement. We are encouraged by these results and believe that our Cellframe technology offers the potential to provide a solution to the unmet medical need in the current standard of care aiming to improve the outcome for these patients. We look forward to further developing this innovative technology and its potential to also address disorders of other hollow organs, such as the bronchus and trachea."

Accepted abstracts will be published in the Transactions of the Society For Biomaterials, a referenced, copyrighted publication of the Society For Biomaterials.

About Cellframe™ Technology

The Company's proprietary Cellframe technology is designed to harness the potential of *their vivo* microenvironment to achieve tissue regeneration and restore organ function. It employs a multi-step process in which the patient's own stem cells are taken from a simple adipose/fat tissue biopsy, expanded and banked, and then seeded onto a proprietary scaffold that mimics the natural dimensions of the organ being regenerated. After several days in a rotating bioreactor, the biocompatible scaffold containing the stem cells is ready to be implanted. Preclinical studies suggest that the organ implant signals the stem cell niche in the surrounding native tissue to guide the regeneration of a biological structure. This technology is based on the concept of *in situ* tissue regeneration using the body's own biologic resources and reparative capability in combination with tissue-specific biomaterials implanted at the sites of disease or injury.

About Cellspan™ Esophageal Implants

Cellspan Esophageal Implants utilize the Company's proprietary Cellframe technology and may offer improved outcomes for patients by potentially simplifying surgical techniques to reduce post-operative complications and improve quality of life, by prompting regeneration of the patient's own esophagus. Cellspan implants are intended to offer numerous advantages over standard surgical resection including: eliminating the use of the stomach or intestine to create a mock esophagus, reduced complications and improve post-surgical morbidity.

About Biostage

Biostage is a biotechnology company developing bioengineered organ implants based on 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 or 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 collaborative preclinical studies. Preclinical, large-animal safety studies, conducted in compliance with the FDA Good Laboratory Practice (GLP) regulations, for the Company's Cellspan Esophageal Implant product candidate are ongoing, in support of Biostage's goal of filing an Investigational New Drug application (IND) with the U.S. FDA in the third quarter of 2017. The IND will seek approval to initiate clinical trials for its esophageal implant product candidate in humans.

For more information, please visit www.biostage.com and connect with the Company on [Twitter](#) and [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 development expectations and regulatory approval of any of our products, including those utilizing our Cellframe technology, 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; 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, 2016 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.

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