The current study tested the biomechanical strength of the newly regenerated esophageal tissue and demonstrated that the strength of the tissue was comparable to adjacent native tissue.

HOLLISTON, Mass., June 15, 2022 /PRNewswire/ -- Biostage, Inc. (OTCQB: BSTG) ("Biostage" or the "Company"), a cell-therapy biotechnology company with successful first-in-human experience repairing the esophagus following cancer surgery and FDA approval to commence a clinical trial of the Biostage Esophageal Implant for severe esophageal disease including cancer, announced today the publication of a paper in the peer-reviewed Journal of Biomechanics, describing a study investigating the mechanical strength of regenerated esophageal tissues. The paper can be accessed here.

The Biostage Esophageal Implant (previously known as Cellspan Esophageal Implant) stimulates the regeneration of new tissue to repair the esophagus following segmental resection of the thoracic esophagus. Using a porcine model, the paper in the Journal of Biomechanics describes a study that tested the mechanical strength of the newly developed tissue as well as the flanking native tissue using a probe-burst pressure test on explanted tissues at three time points post-implantation. The BEI bridged the proximal and distal native esophageal ends to restore the conduit by stimulating a regeneration process that progressed from a fibrovascular scar at 30-days to a fully epithelialized lumen at 90-days, followed by submucosal regeneration and regeneration of a 'laminated' adventitia with smooth muscle development in the 365-day cohort. The burst strength of the regenerated tissues at all three time points were comparable to the native tissue flanking the implant and the overall pressure required to burst through the tissue increased with increasing time post-surgery.

David Green, Interim Chief Executive Officer of Biostage, commented: "We are pleased to publish this paper in Journal of Biomechanics. We believe this publication shows that the Biostage Esophageal Implant (BEI) stimulates the body to regenerate the esophagus and that the regenerated tissue is comparable in strength to the native esophagus."

Dr William Fodor, Chief Scientific Officer of Biostage, added: "Presenting evidence that the mechanical strength of the regenerated tissue was comparable to the native tissue is a critical finding and a key question from the FDA related to the safety of the technology. In collaboration with Exponent, Inc., the paper demonstrates that the new tissue can withstand burst pressures similar to the native tissue, as early as 30 days post implantation and throughout the one-year study. These results helped to establish a favorable safety profile, which was an integral component of our approved IND."

About Biostage.

Biostage is a clinical-stage biotech company that uses cell therapy to regenerate organs inside the human body to treat defects due to cancer surgery, trauma, end-stage disease or birth defects in the esophagus and potentially other tubular organs.

Biostage has 8 issued U.S. patents, 2 orphan-drug designations (which provide 7 years of market exclusivity in addition to any patents), and the possibility of 2 Priority Review Vouchers from the FDA.

Biostage's current goals include raising capital, uplisting from the OTC bulletin board to Nasdaq and beginning its clinical trial

for regeneration and repair of the esophagus.

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 capabilities and performance of our products and product candidates, including the strength of regenerated tissue; our capital raising plans and expectations, including uplisting to Nasdaq; development expectations and regulatory approval of any of the Company's products, including those utilizing its Biostage Esophageal Implant 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; 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, 2021 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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