Biostage Submitted Official Response to FDA for Investigational New Drug Application for its Lead Product Candidate Cellspan™ Esophageal Implant

HOLLISTON, Mass., Feb. 20, 2020 /PRNewswire/ -- Biostage, Inc. (OTCQB: BSTG) ("Biostage" or the "Company"), a bioengineering company developing next-generation esophageal implants, today announced that it has submitted its official response to the formal letter from the U.S. Food and Drug Administration (FDA) related to the Company's Investigational New Drug (IND) application for the Cellspan Esophageal Implant (CEI).

The formal letter from the FDA received on December 26th noted that the agency will inform Biostage of its decision within 30 days of the Company's submission of its formal response.

"I am extremely pleased with our advancements in the development of the Cellspan Esophageal Implant and our efforts towards a 'First-in-Human' clinical trial as a potential new therapeutic option for patients with end-stage esophageal disease. In addition, we believe that these advancements will position us to move forward with our CEI into Esophageal Atresia, a congenital defect in children where they are born without a fully functional esophagus," said Jason Jing Chen, Biostage's Chairman. "I would especially thank William Fodor, our Chief Scientific Officer, who managed the substantial and timely responses and interaction with the FDA along with the R&D team at Biostage who have worked long hours to complete the IND submission. We also extend thanks to Jim McGorry, our former Chief Executive Officer.

"As we reported back in October of 2019, the submission of Biostage's first IND for our lead product candidate, the Cellspan Esophageal Implant, was a significant achievement for our team and a major milestone for the company," commented Dr. Fodor. "As we also reported, we received an official notification from the FDA on December 26, 2019, that we were being placed on Clinical Hold until we addressed questions and requests for more information from the agency. We are pleased to announce today that our responses were submitted with the help of our clinical advisors and input from our Scientific Advisory Board. Our thanks go out to all of our advisors and to Boston Biomedical Associates, our regulatory consulting group, who assisted in the submission process. We look forward to updating you on the FDA's decision following the 30-day review period."

About Biostage, Inc.

Biostage is a bioengineering company that is developing next-generation esophageal implants. The Company's Cellspan technology combines a proprietary, biocompatible scaffold with a patient's own cells to create an esophageal implant that could potentially be used to treat pediatric esophageal atresia and other conditions that affect the esophagus. The Company's esophageal implant leverages the body's inherent capacity to heal itself as it is a "living tube" that facilitates regeneration of esophageal tissue and triggers a positive host response resulting in a tissue-engineered neo-conduit that restores continuity of the esophagus. These implants have the potential to dramatically improve the quality of life for children and adults. At Biostage, we believe the future of medicine has been inside us all along.

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 our financing activities; development expectations and regulatory approval of any of the Company's products, including those utilizing its Cellspan and 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 the Company's products, including those utilizing its Cellspan and 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, 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, 2018 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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