

## **Biostage Receives Response from the FDA for Investigational New Drug Application for its Lead Product Candidate Cellspan™ Esophageal Implant**

HOLLISTON, Mass., Dec. 3, 2019 /[PRNewswire](#)/ -- [Biostage, Inc.](#) (OTCQB: BSTG) ("Biostage" or the "Company"), a bioengineering company developing next-generation esophageal implants, today announced that it was notified via email on November 27, 2019 by the U.S. Food and Drug Administration (FDA) that the Company's Investigational New Drug (IND) application for its lead product candidate, the Cellspan Esophageal Implant (CEI), has been placed on clinical hold.

As the Company anticipated, Biostage received questions from the FDA following its IND application in late October. Biostage provided preliminary responses to these questions and notified the agency that a complete response would follow. The FDA's November 27<sup>th</sup> message noted its understanding that additional time is needed to fully answer the agency's questions, and that the FDA will send a more detailed letter regarding the application's hold status within 30 days. The Company is working to finalize responses to the FDA questions.



### **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 Cellspan esophageal implant leverages the body's inherent capacity to heal itself. The CEI is implanted as a cellular 'living tube' delivered via a temporary removable scaffold cell delivery device. The CEI 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](http://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.

### **Investor Relations Contact**

Peter Chakoutis  
Vice President of Finance  
774-233-7300  
[pchakoutis@biostage.com](mailto:pchakoutis@biostage.com)

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