New Paper Shows Biostage's Esophageal Implant Regenerates the Esophagus in Piglets
Establishes the basis for a clinical trial in human babies with birth defects in the esophagus.

HOLLISTON, Mass., Jan. 10, 2022 /PRNewswire/ -- Biostage, Inc. (OTCQB: BSTG) ("Biostage" or the "Company"), a biotechnology company with successful "first-in-human" experience in esophageal cancer and FDA approval to commence a clinical trial of its Biostage Esophageal Implant for esophageal disease, today announced the publication of paper establishing the basis for using its product to treat birth defects in the esophagus in babies.

The paper(1) was published today in Nature Partner Journals Regenerative Medicine and concludes that the Biostage Esophageal Implant, "is safe and well tolerated". By three weeks after surgery a continuous tube had been regenerated, by 3 months a complete mucosal lining was seen and by one year, "it was difficult to distinguish neo-tissue vs. the native tissue".

The piglets gained weight steadily over the course of the study and eventually tripled their size, showing that the regenerated esophagus grows with the patient.

The paper states that current techniques for repairing birth defects in the esophagus, "have significant costs, complication rates, lengthy hospital stays, and significant morbidities. Therefore, the development of novel approaches that bridge a primary long gap…are highly desired." Dr. Christine Finck, Surgeon in Chief, Connecticut Children's Medical Center, who performed the surgeries, said "this technology has the potential to provide a novel therapy for some of our must fragile patients."

Biostage has previously reported on the first-in-human regeneration of an esophagus in an adult cancer patient, performed at Mayo Clinic and published in JTO Clinical and Research Reports in August 2021(2). That paper concluded that the Biostage Esophageal Implant would have, "considerable clinical use."

The FDA has already approved a 10-patient, phase 1/2 clinical trial for repair of the esophagus in adults. The FDA has indicated a willingness to consider expanding the current clinical trial to include pediatric subjects once the safety of the implant is shown in adults. Hence, we expect the repair of birth defects in the esophagus to be an additional indication for which Biostage will seek FDA approval.

In the U.S., there are approximately 1,000 babies born each year with defects in the esophagus. Approximately 100 of these would be eligible for treatment with the pediatric Biostage Esophageal Implant. In addition, we believe that our product would be used in additional cases where the primary treatment has failed. The small size of the pediatric population makes the treatment eligible for a Priority Review Voucher from the FDA. These vouchers are transferrable, and a sale of such voucher could provide a significant source of non-dilutive financing for Biostage.

David Green, Biostage's founder and former CEO, who was recently appointed as Chairman of the Board and rehired as interim CEO said, "This ground-breaking work should allow us to treat babies born with birth defects in the esophagus as well as adults with cancer or trauma in the esophagus. I am very proud of our team that has performed this research in collaboration with our long-time partner in pediatric indications, Connecticut Children's Medical Center. Bringing hope to patients like these is why I rejoined Biostage." Connecticut Children's Medical Center is also an investor in Biostage.
About Biostage.

Biostage is a clinical-stage biotech company that uses cell therapy to regenerate organs inside the human body to treat cancer, trauma and birth defects. We have performed the world's first regeneration of an esophagus in a human cancer patient. This surgery was performed at Mayo Clinic and was published in August 2021.

Biostage has 7 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 repair of the esophagus in adults.

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 success with respect to any collaborations, clinical trials and other development and commercialization efforts of the Company's products, which success may not be achieved or obtained on a timely basis or at all; our financing activities; and our 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. 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, 2020 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

Shunfu Hu
Vice President of Business Development and Operations
774-233-7300
shu@biostage.com

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SOURCE Biostage, Inc.