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Biostage gives update on FDA Investigational NDA for Cellspan Esophageal Implant

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Biostage Provides Update on FDA Investigational New Drug Application for its Lead Product Candidate Cellspan™ Esophageal Implant

Biostage, a bioengineering company developing next-generation esophageal implants, received the anticipated formal response 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).

This anticipated letter, received December 26th, details specific questions and clarifications that will enable Biostage to complete and submit its formal reply. Biostage received a preliminary communication from the FDA on November 27th, allowing the Company to begin preparing its responses.

"Our R&D team is expeditiously finalizing our responses," said Jim McGorry, CEO of Biostage. "Prior to receiving approval to begin testing human subjects for a first-in-human trial, multiple rounds of communication with the FDA are anticipated and routine. Entering the clinic is our greatest priority and we will provide an update as soon we receive approval from the FDA."

The FDA noted in its letter that it will inform Biostage of its decision within 30 days of the Company's submission of its formal response.