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FOR IMMEDIATE RELEASE

LSNE SUCCESSFULLY COMPLETES FDA PAI AND GENERAL GMP INSPECTION OF TWO ASEPTIC MANUFACTURING PLANTS AND QC LABORATORY

Bedford, NH – Lyophilization Services of New England, Inc. (LSNE) announced today the successful completion of two FDA inspections of their aseptic manufacturing facilities. These inspections were conducted in January and February of 2017. The first inspection was an FDA Pre-Approval Inspection (PAI) of their aseptic manufacturing facility located at Commerce Drive in Bedford, NH. As a result, the Commerce Drive facility has been recommended for approval to manufacture the commercial sterile drug product for US distribution. This PAI, which also served as a general GMP inspection, included both the multi-product aseptic manufacturing site as well and the supporting QC laboratories. The second inspection was a general GMP inspection of LSNE's Harvey Road aseptic manufacturing facility which is also located in Bedford, NH. The Harvey Road facility is dedicated to the aseptic filling and lyophilization of a product that is commercially approved by the FDA and currently on the market. Both inspections resulted in no Form 483 being issued for either facility, as there were no observations noted by the FDA.

Shawn Cain, Chief Operating Officer of LSNE stated, "We are very pleased with the positive results of the latest FDA inspections of our two aseptic manufacturing sites and supporting QC laboratories. We are proud to say that the most recent inspections of our three manufacturing sites have all resulted in no observations. This also marks the second consecutive inspection of the Harvey Road facility with no observations and the second consecutive recommendation for approval at the Commerce Drive location. We believe that our compliance history demonstrates our commitment to constantly improve our systems and to staying current with the ever changing regulatory landscape".

LSNE has added additional capabilities across all three of their manufacturing sites in 2016 and they plan to continue expanding in 2017. The 2017 master plan includes expansion of its QC laboratory and centralized warehousing with expanded cold chain capabilities, additional complex/potent compound handling capabilities, as well as increased large scale commercial fill/finish and lyophilization capacity. LSNE continues its path towards becoming the premier turn-key CMO for clinical and commercial clients and always strives to reduce the time and cost of bringing clients projects from bench top to market.

About LSNE Contract Manufacturing

LSNE Contract Manufacturing is a privately held company with three GMP facilities located in New England. LSNE has been providing contract lyophilization services to the pharmaceutical, biotechnology and medical device industries since 1997, specializing in a wide range of services including cycle development, cGMP fill/finish, and lyophilization. Through the thoughtful integration of three

processing facilities, qualified staffing, and an extensive manufacturing history, LSNE is strategically positioned to provide uninterrupted manufacturing for clinical through commercial supply for medical device and pharmaceuticals to a multi-national market.

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