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FOR IMMEDIATE RELEASE

LSNE-LEÓN COMPLETES SUCCESSFUL FDA PRE-APPROVAL INSPECTION FOR STERILE INJECTABLE

FDA Pre-Approval Inspection for Pre-Filled Syringe Product
Completed with No Form 483 Observations

January 21, 2020, Bedford, NH – LSNE Contract Manufacturing (LSNE), a privately held contract development and manufacturing organization, is pleased to announce a successful Pre-Approval Inspection (PAI) performed by the US Food and Drug Administration (FDA) at its aseptic fill finish facility in León, Spain. The inspection took place this month and LSNE was found to be compliant with no Form 483 observations issued. LSNE-León is now positioned to support commercial manufacturing of a sterile injectable product in a pre-filled syringe presentation.

“This inspection was a critical milestone for LSNE and its newest site within LSNE’s global network. This marks the second successful FDA inspection at LSNE-León and demonstrates the site’s alignment and commitment to LSNE’s core values of quality and compliance” said Tom McGrath, VP of Quality & Regulatory.

Shawn Cain, Chief Operating Officer said, “We are proud of our León team and to add another successful inspection to our long track record of compliance. As we continue to grow, quality is always at the forefront of our business so that we can best serve our clients and their patients. It is only through the hard work and dedication of our team that we have been able to achieve and maintain this high level of integrity, quality, and consistency.”

About LSNE

LSNE is a privately held company with six cGMP facilities – four located in New Hampshire, one in Wisconsin and one located in León, Spain. 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 lyophilization cycle development, cGMP fill finish, and lyophilization. Through the thoughtful integration of six processing facilities, qualified staffing, and an extensive manufacturing history, LSNE is strategically positioned to provide products and services for clinical through commercial supply for pharmaceuticals and medical devices to a multi-national market.

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