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FOR IMMEDIATE RELEASE

LSNE Announces GMP Certification by Brazil's ANVISA

May 14, 2019, Bedford, NH – Lyophilization Services of New England (LSNE), a leading contract development and manufacturing organization (CDMO) specializing in pharmaceuticals and medical devices, announced today that it has received Good Manufacturing Practices (GMP) certification from Brazil's National Health Surveillance Agency - ANVISA (Agência Nacional de Vigilância Sanitária) following an inspection and audit of its manufacturing facility in Manchester, NH in February 2019. This now allows LSNE's clients to export medical devices to Brazil and is the first LSNE manufacturing facility to receive ANVISA certification.

Brazil's GMP regulations, which closely resemble the internationally recognized ISO 13485 standard, require medical device manufacturers to have a robust quality system for the design, manufacture, packaging, labeling and storage of their products, among other requirements.

"LSNE is very pleased with the successful completion of the ANVISA inspection and GMP certification of our Manchester Medical Device manufacturing facility. Our strict adherence to GMP and our quality systems allows LSNE to provide our clients with a high-quality product on time." Said Matthew Halvorsen, Chief Executive Officer, Founder and President of LSNE. "Our certification from ANVISA, represents an important milestone in being a premier CDMO and our continued commitment to quality and patient safety."

About LSNE

LSNE is a privately held company with four GMP manufacturing facilities – three located in New England and one in Madison, WI. 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 four 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.

About ANVISA

ANVISA is responsible for drug registration and licenses for pharmaceutical laboratories and other companies within the pharmaceutical production flow. The agency also is responsible for establishing

regulations that apply to clinical trials and drug pricing. Together with states and municipalities, the agency inspects factories, monitors the quality of drugs, exercises post-marketing surveillance, takes pharmacovigilance actions, and regulates drug promotion and marketing.

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