

News Release

Philadelphia, PA USA November 11, 2011

Lyophilization Technology, Inc. completes the clinical trial material manufacturing campaign of a new lyophilized vaccine. This advanced form of a highly purified novel vaccine, developed by a leading vaccine company in Japan promises to provide highly effective protection from a severely debilitating infection while exhibiting a superior patient safety profile.

Requirements for preparation of this new vaccine entailed challenging manufacturing methods, including viral deactivation of starting materials, aseptic compounding, and accurate and precise fill weights to a fraction of a milliliter, with maximum yield during manufacturing. Critical Quality Attributes meet stringent US and EU requirements and the expectations for a product as produced by a Japanese vaccine manufacturer.

The close collaboration between the study sponsor and LTI was a key factor in the success of the project. Integrating manufacturing methods developed at the sponsor's facility in Japan into the clinical manufacturing operations at LTI required clear communication and close attention to every detail. In addition, the coordination between the study sponsor, LTI, various specialty US and international testing laboratories, and clinical labeling and packaging organizations was also key to the success of the project.

Ready for clinical trials in the United States in 2012, this new prophylactic vaccine has great potential throughout the world for prevention of a concerning disease for which there is no specific therapeutic treatment. Ed Trappler, President of LTI summarized the project: "The capabilities and dedication of the staff was repeatedly demonstrated throughout this project. Successfully overcoming the manufacturing challenges was highly rewarding, particularly when considering the significance of this new vaccine. Meeting the demanding requirements in producing this new product of such great importance and impact exemplifies the essence of the mission for the staff at LTI. We have been pleased to have the opportunity to collaborate with our colleagues in Japan and look forward to successful clinical outcomes for this important new vaccine."

About Lyophilization Technology: Lyophilization Technology provides scientific services and technical support in freezing and freeze drying for the health care and related industries involved in producing pharmaceuticals, biologics, diagnostics, biopharmaceuticals, and medical devices. Since its founding in 1992, the company has grown to provide a wide variety of services in diverse applications of the technology. Scientific services consist of development, clinical material preparation, optimization and troubleshooting lyophilized products and processing. Services provided to the industry also include transferring newly developed and currently marketed products to multiple manufacturing sites, streamlining operations and improving regulatory compliance stature. Contact LTI at www.lyotechnology.com for further information.