



Optimization of Supercritical Carbon Dioxide Based Virus Inactivation, Characterized by Protein Damage and Maintenance of Epitope Integrity in Vaccine Sterilization

(Lansing, NY; June 22, 2015) – NovaSterilis Inc., an industry leader in developing applications for supercritical carbon dioxide (SCCO₂), has been awarded a NIH, NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES Phase I grant to optimize virus inactivation using supercritical carbon dioxide while limiting protein damage and maintaining epitope integrity in recombinant Virus-Like Particle vaccines.

Sterilization of medical devices and materials is central to the effort to reduce or eliminate infections but the majority of this effort has been spent to understand bacterial inactivation. NovaSterilis has a strong interest in understanding the Supercritical CO₂ Sterilization processes ability to inactivate all pathogens including viral, fungal and yeast pathogens.

NovaSterilis has completed two NIH Phase II grants validating Supercritical CO₂ Sterilization of allograft tissue and absorbable sutures. These data demonstrated the ability to achieve a sterility assurance level of 10⁻⁶ or SAL6, the industry standard for medical devices while preserving the vital product characteristics. The achievement of SAL6 demonstrates a probability that one item in one million could be contaminated with a bacterial spore, but does not consider viral pathogens. For this grant Dr. Julien Fey NovaSterilis Director of Research and Development is collaborating with Dr. Bryce Chackerian at the University of New Mexico Department of Molecular Genetics and Microbiology. Dr. Chackerian is a leading scientist in the development of innovative vaccines based on Virus-like Particles against chronic and infectious diseases.

The goal of this research is to identify the mechanism of inactivation of viral pathogens with NovaSterilis Supercritical CO₂ sterilization and to refine our technology to develop a process applicable to the production of inactivated vaccines, and the final sterilization of labile biopharmaceuticals and sub-unit vaccines. This work will provide an understanding of methods mitigating protein damage in the sterilization process which will have broader applications, including protecting enzymes and growth factors in supercritical-based tissue engineering.

“Building on our success with identifying the mechanism of inactivation of bacterial spores, NovaSterilis is moving this technology forward with the goal of utilizing the process not only for sterilization but also for the production of vaccines, stated David Burns President and CEO of NovaSterilis. We have a history of collaborating with experts in their field; in this instance we are working with Dr Chackerian a leader in

vaccine development; particularly the use of virus particles as platforms for antigen display.”

Current SCCO₂ applications

NovaSterilis technology is being utilized by both US and International Tissue Banks to produce sterile allograft tissue in final double packaging ready for transplantation, to date over 70,000 SCCO₂ sterilized allograft transplants have been performed with no adverse reports. This sterilization technology is currently employed for sterilization of 2 medical devices with regulatory approval. NovaSterilis is now offering a larger 80 liter SCCO₂ sterilization unit, the Nova8800, to meet the high throughput needs of larger tissue processors and medical device manufacturers. NovaSterilis’ SCCO₂ process provides the medical materials industry with a safe, effective, in house, low cost terminal sterilization alternative.

About NovaSterilis

NovaSterilis currently markets terminal sterilization technology and equipment related to their supercritical carbon dioxide platform. The supercritical or fluid phase of CO₂, occurs at low pressure (72.9 atm) and moderate temperatures (31.1 °C). SCCO₂ retains advantageous properties of the gas and liquid phases of carbon dioxide making it an ideal fluid for manufacturing processes. The company currently markets the Nova 2200 (20 liter) and Nova8800 (80 liter) fully automated SCCO₂ terminal sterilization equipment. NovaSterilis is a privately held biotechnology company located in Lansing New York. NovaSterilis is the recipient of a 2007 Presidential Green Chemistry Challenge Award presented by the Environmental Protection Agency.

****(SAL6)** – Sterility Assurance Level 10⁻⁶ is a standard for medical devices. It is the probability of 1 non-sterile item in 1 million.

For more information on NovaSterilis and supercritical carbon dioxide visit www.novasterilis.com or call 607-330-2771