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Press Release

NovaSterilis Awarded Patent for Sterilization Process for Pharmaceutical API using Supercritical Carbon Dioxide

(Lansing, NY; September 19, 2011) – NovaSterilis Inc., a developer of supercritical carbon dioxide technology, has been granted US Patent No 8,012,414 B2. The patent, dated September 6, 2011 is entitled "Sterilization of Drugs Using a Supercritical Carbon Dioxide Sterilant" covers a new and effective method of sterilizing pharmaceutical product without dangerous chemicals or radiation.

The patent describes the use of a proven novel sterilization apparatus together with chemical additive(s) to sterilize active and inactive pharmaceutical ingredients achieving a 6-log reduction in bacteria and bacterial spores while maintaining the vital crystalline structure and chemical activities of these compounds.

"The pharmaceutical industry discovers and manufactures treatments and cures from a wide range of natural and synthetic compounds, these products are sourced from all over the globe and this invention provides an effective high level sterilization process for these life saving pharmaceuticals," noted David Burns, President of NovaSterilis. "We are excited about this patent; it provides a new method for achieving a Sterility Assurance Level of 10^{-6} (SAL6) without the use of toxic carcinogenic chemicals, or the degradation of radiation sterilization providing this innovative industry with an effective alternative to current methods.

NovaSterilis is currently commercializing other patents based on supercritical CO_2, including terminal sterilization of biomedical materials. This technology is being utilized by multiple US and International tissue banks to produce sterile allograft tissue in final double packaging ready for transplantation. This patent validates an additional application of NovaSterilis technology utilizing the knowledge and experience gained from our allograft and biomedical material sterilization work. NovaSterilis prior experience with $SCCO_2$ allowed their research and development team to overcome specific limitations encountered while working with delicate drug molecules, by altering pressure or temperature at specific time points in the cycle NovaSterilis achieved sterilization while protecting the unique crystalline structure of specific active pharmaceutical ingredient(s) (API). Proof of concept work was completed with active drug product in the industry standard packaging providing a clear path to commercializing this application.

Recent experiments at NovaSterilis utilizing larger scale $SCCO_2$ units provided important data to support the scale up of this technology to meet the high throughput needs of the pharmaceutical industry, Current sterilization of API is limited to either; gamma irradiation which can degrade products, or ethylene oxide (EtO) a highly toxic, carcinogenic, environmentally dangerous, and extremely volatile gas. Several governments are increasing regulations on the use of EtO to limit environmental release and reduce acceptable residual chemical levels. NovaSterilis supercritical CO_2 provides the medical materials industry a new, 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 CO_2, occurs at low pressure (72.9 atm) and moderate temperatures (31.1° C). Supercritical CO_2 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, a 20 liter fully automated supercritical CO_2 terminal sterilization chamber and is in final development of an 80 liter unit. 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.

For more information on NovaSterilis and supercritical carbon dioxide visit www.novasterilis.com