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Press Release

NovaSterilis Wins 2007 Presidential Green Chemistry Challenge Award for Environmentally Benign Medical Sterilization Using Supercritical Carbon Dioxide

WASHINGTON DC, July 27th, 2007 – **NovaSterilis**, a privately held biotechnology company in Ithaca, NY, has received the 2007 Presidential Green Chemistry Challenge Award in the small business category from the U.S. Environmental Protection Agency. The awards recognize important and innovative scientific solutions to real-world environmental problems involving the manufacture and use of chemicals. The award was presented in a ceremony at the National Academy of Sciences on June 26th, 2007.

Sterilizing biological tissue for human transplant surgery is critical to the safety and success of such procedures. Each year about 1.5 million 'aseptically processed' musculoskeletal tissue allografts are distributed to transplant surgeons by U.S. tissue banks. Occasionally, transplants of contaminated donor tissue have resulted in serious infections, illnesses and even deaths in patients.

To date, no known method for medical sterilization can be used to sterilize packaged allograft tissue and other delicate biological materials without eroding their structural integrity. The two most common terminal sterilization techniques use ethylene oxide or gamma radiation, which are toxic or have safety problems. Ethylene oxide is a mutagenic, carcinogenic, volatile, flammable reactive gas. Residues of ethylene oxide remain in the sterilized material, increasing the risk of toxic side effects. Gamma radiation is highly penetrating and alters the structure of biological materials.

NovaSterilis successfully developed and commercialized a highly effective and environmentally benign method for sterilizing delicate biological materials using supercritical carbon dioxide. The company's Nova2200™ sterilizer requires neither hazardous ethylene oxide nor gamma radiation, and consistently achieves rapid and total inactivation of a wide range of microbes, including bacterial endospores. The new technology is compatible with a wide range of important biomedical materials including (a) musculoskeletal allograft tissue (e.g., human bone, tendon, dermis, heart valves) for transplantation; (b) biodegradable polymers and related materials used in medical devices, instruments and drugs; (c) drug delivery systems; and (d) whole-cell vaccines.

NovaSterilis licensed a patent for bacterial inactivation in synthetic polymers that was issued to Professor Robert S. Langer and colleagues at the Massachusetts Institute of Technology. **NovaSterilis** then enhanced, expanded, and optimized the technology to kill bacterial endospores. Their supercritical CO_2 technology uses low temperatures and moderate pressure along with small amounts of a synergistic additive.

Besides being a green chemical technology, supercritical CO_2 sterilization achieves "terminal" sterilization, that is, sterilization of the final packaged product. Terminal sterilization provides greater assurance of sterility than traditional methods of aseptic processing. Sterilization of double-bagged tissue allows tissue banks to ship terminally sterilized musculoskeletal tissues in packages that can be opened in operating rooms by surgical teams immediately prior to use. **NovaSterilis's** patented technology addresses the market need in tissue banks as well as other needs in the biomedical, biologics, medical device, pharmaceutical, and vaccine industries. **NovaSterilis** has sold several Nova2200™ units to leading U.S. tissue banks.