

## **KensaGroup, Inc. Announces Licensing Agreement For Supercritical Fluid Sterilization Technology**

**A New Technique with Many Promising Biomedical Applications,  
Including Polymeric Materials and Drug Delivery**

*ITHACA, NY, February 11<sup>th</sup>, 2001* – KensaGroup, Inc. announced that it has acquired an exclusive license for the use of supercritical carbon dioxide (CO<sub>2</sub>) in the sterilization of materials, including macromolecular and polymeric materials for use in biomedical applications. The technology, developed by Angela Dillow, Neil Foster, Jeffrey S. Hrkach, and Robert S. Langer, Jr., was licensed from the Massachusetts Institute of Technology. Terms of the licensing agreement have not been disclosed.

The most common methods of bacterial inactivation (sterilization) consist of superheated steam, ethylene oxide treatment, UV-irradiation, or gamma-irradiation. None of these methods is well-suited to the sterilization of synthetic, polymer-based materials, which are increasingly being used in modern medicine, especially for controlled-release drug delivery, tissue implants, and orthopaedic devices. For example, the high temperatures required for autoclaving can decompose encapsulated drugs or other sensitive biologics. Similar losses in activity result from UV-irradiation.

Sterilization with gaseous ethylene oxide may leave residual material in the polymer, which can cause hemolysis or other toxic reactions. Ethylene oxide can also react with proteins and nucleic acids, which are increasingly being developed as drugs. Gamma radiation may alter the elasticity or tensile strength of polymers, and damage other labile biological materials.

“We are extremely pleased to have reached this agreement with the Technology Licensing Office at M.I.T.,” said Dr. Bruce Ganem, Chief Scientific Officer of KensaGroup, Inc., “With the ever more sophisticated biomedical engineering that goes into new product development, the need for mild, yet effective, sterilization techniques is becoming acute. Because of its unique mass transfer properties, supercritical CO<sub>2</sub> can permeate cell walls and other materials. Besides the obvious applications to controlled-release drug delivery systems, we believe supercritical CO<sub>2</sub> will also find use in the post-packaging sterilization of materials like catheters and stents, and will have a profound impact on the manufacturing process.”