



**THERMOGENESIS CORP. MEETS CLINICAL ENDPOINTS  
OF PHASE III CLINICAL TRIAL OF CRYOSEAL®  
FIBRIN SEALANT (FS) SYSTEM**

**RANCHO CORDOVA, California (October 25, 2005) – ThermoGenesis Corp. (NASDAQ: KOOL)** announced today that the outcome data are now complete for its pivotal U.S. 150-patient blinded, randomized, multi-center clinical trial for the CryoSeal FS System. This pivotal trial evaluated the safety and efficacy of the fibrin sealant prepared by the CryoSeal FS System as an adjunct to hemostasis for cancer patients undergoing liver resection surgery against a control, Instat, a collagen absorbable hemostat. The lead Principal Investigator was Dido Franceschi, MD, Associate Professor of Surgery, University of Miami.

The study reached its primary end point, which was to demonstrate equivalency (i.e. that results obtained using the CryoSeal FS System were “non- inferior” to results achieved with Instat). Not only did the data show statistical significance for “non-inferiority”, but also that patients treated with CryoSeal FS actually showed “superiority”, demonstrating statistically significant quicker time to hemostasis (cessation of bleeding) versus the control group (p-value= <0.001).

	<u>CryoSeal FS</u> N=100	<u>Control</u> N=53
Median time to hemostasis +/-S.D.	3.43 +/-3.41 min.	8.65 +/-10.18 min.
Patients achieving hemostasis in < 10 min.	92.00%	60.40%

In addition, in this study, no unanticipated adverse device effects (UADEs) were reported by the physician to either the study or control materials. These data will be included in a Pre-Market Approval (PMA) submission that ThermoGenesis expects to file in December 2005. The review process of a PMA submission typically takes less than one year.

This clinical trial was managed by Quintiles Inc., the North American clinical development subsidiary of Quintiles Transnational Corp., who engaged thirteen (13) prominent cancer centers including; Cedar-Sinai Medical Center, Johns Hopkins Cancer Center, Lahey Clinic, Memorial Sloan-Kettering Cancer Center, Mount Sinai School of Medicine, New York University Medical Center, St. Vincent Medical Center, University of California Los Angeles Dumont Liver Cancer Center, University of Illinois at Chicago Medical Center, University of Louisville School of Medicine, University of Miami Sylvester Cancer Center, University of Southern California Medical Center, and Vanderbilt University Medical Center.

FDA approval would enable ThermoGenesis to address the \$125 million U.S. fibrin sealant market as well as other international markets that allow FDA-cleared products to be sold within their borders. The worldwide market for fibrin sealant exceeds \$450 million per year.

Kevin Simpson, President and COO of ThermoGenesis Corp. noted, “We are pleased with the encouraging results of this long awaited trial. The “superiority” results of these data indicate that physicians performing liver surgery will have an option to accelerate the hemostasis process. With these data, we will now move forward confidently in submitting our PMA on plan by the end of this calendar year.”

The CryoSeal FS System prepares both components (cryoprecipitate and thrombin) of CryoSeal Fibrin Sealant from a single unit of autologous human plasma in about an hour. Once prepared, the CryoSeal Fibrin Sealant may be frozen or used immediately as a hemostatic agent for patients undergoing liver resection surgery.

In contrast, conventional fibrin sealants are sourced from large pools of 10,000 or more units of purchased plasma, and thus remain vulnerable to contamination by infectious pathogens residing in any of these 10,000 units of blood plasma. There have been several recent peer-reviewed journal reports of the transmission of Parvo virus B-19 to surgical patients receiving conventional fibrin sealant. In addition, conventional fibrin sealants often contain animal proteins such as bovine aprotinin. Animal proteins are a potential source of agents of transmissible bovine spongiform encephalopathy (BSE), which are resistant to any methods of pathogen inactivation available to fractionators at this time.

### **Regulatory Status**

ThermoGenesis Corp. has been granted the right to affix the CE Mark to the CryoSeal FS System by our European Notified Body. The product is being tested in European clinical trials. Additional field trials are underway in Canada and Brazil. In Japan, the pivotal clinical trial was completed in late 2004 and the PMA filed in March 2005. Sales in the U.S. must follow FDA approval. The submission of a PMA is expected in 2005 and based on that submission the Company could receive FDA approval to market in 2006.

### **About ThermoGenesis Corp.**

ThermoGenesis Corp. is a leader in enabling technologies for cell therapeutics. The Company's technology platforms lead the world in their ability to produce biological products from single units of blood.

- The **BioArchive® System**, an automated robotic cryogenic device, is used by major cord blood stem cell banks in 26 countries as a key enabling technology for cryopreserving and archiving stem cell units for transplant.
- The **AutoXpress™ System**, currently undergoing Alpha testing, is a semi-automated robotic device and companion sterile closed blood processing disposable, to harvest stem cells from cord blood.
- The **CryoSeal FS System**, a semi-automated device and companion sterile blood processing disposable, is used to prepare hemostatic and adhesive surgical sealants from the patient's blood in about an hour. Enrollment in a 150 patient U.S. pivotal clinical trial has been completed and a PMA is being prepared.
- The **Thrombin Processing Device (TPD™)** is a sterile blood processing disposable that prepares activated thrombin from a small aliquot of patient blood, or blood plasma in 25 minutes. The TPD market launch is underway in Europe.

*The statements contained in this release which are not historical facts are forward-looking statements that are subject to risks and uncertainties that could cause actual results to differ materially from those expressed in the forward-looking statements, including, but not limited to, certain delays beyond the company's control with respect to market acceptance of new technologies and products, delays in testing and evaluation of products, and other risks detailed from time to time in the Company's filings with the Securities and Exchange Commission.*

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