U.S. FDA grants Arsenal Medical investigational device exemption approval to conduct clinical ResQFoam™ study

Watertown, Mass., June 5, 2017 – Arsenal Medical announces today that they have received unconditional IDE approval from FDA to conduct a clinical study to examine the safety and effectiveness of ResQFoamTM, a self-expanding material for the treatment of severe internal bleeding in trauma patients. This study will take place in trauma centers throughout the United States and is supported by funding from the US Army Medical Research and Materiel Command (USAMRMC). The study is designed to support ultimate product approval in the United States.

ResQFoam is a biocompatible, self-expanding biomaterial, designed to be administered at the point of injury to stop massive blood loss in patients suffering from life-threatening abdominal trauma. The material fills and conforms to the abdominal cavity to control bleeding before being removed at the time of surgery. ResQFoam may provide a life-saving bridge to surgical care for those who may otherwise die before reaching surgical care, both in civilian and military settings. Abdominal bleeding accounts for the majority of preventable fatalities in injured warfighters.

“Many patients and military personnel with massive abdominal bleeding will die before they reach surgical care,” said Dr. David King, the Principal Investigator for the study, a trauma surgeon at Massachusetts General Hospital, and a Lieutenant Colonel in the US Army. “Quickly stabilizing these patients can substantially increase their chances of survival.” As a trauma surgeon in the army, Dr. King has served multiple tours of duty in Iraq and Afghanistan. He and his research team have collaborated with Arsenal Medical on the development of ResQFoam.

The pre-clinical data on the ResQFoam device has been described in more than ten peer-reviewed manuscripts and at several national trauma conferences. After review of this data, the Food and Drug Administration approved an investigational device exemption (IDE) enabling clinical study of ResQFoam in severely injured trauma patients.

The study will be conducted at multiple trauma centers throughout the United States. “Even in our most capable hospitals, almost half of the patients with severe abdominal trauma die before reaching the operating room,” said King. “By conducting the clinical study in these hospitals, we can obtain robust data on the safety and effectiveness of ResQFoam.”

“A clinical study of ResQFoam has the potential to save lives while obtaining critical data on the safety and effectiveness of the device.” said Dr. Upma Sharma, Program Director for the USAMRMC contract and Vice President of Research and Development at Arsenal Medical. “This clinical study is the next critical step to an FDA approval, which will enable the use of this device to save patients with injuries who might otherwise die prior to reaching surgical care.”

ABOUT ARSENAL MEDICAL

Arsenal Medical is a privately held life sciences company developing advanced biomaterials to improve medical care. The company is advancing multiple therapeutic programs based on its proprietary therapeutic foam technology in trauma and cardiovascular medicine. Arsenal

Medical's investors include Polaris Partners, North Bridge Venture Partners and Intersouth Partners.

ABOUT USAMRMC

The U.S. Army Medical Research and Materiel Command (USAMRMC) is responsible for medical research, development, acquisition, and logistics management for the Army. USAMRMC supports research, development, contracting, and strategic logistics in fields including infectious diseases, combat casualty care, military operational medicine, medical chemical and biological defense, and clinical and rehabilitative medicine. USAMRMC has funded the advanced development of ResQFoam through a contract awarded in 2015.