BiO2 Medical Receives IDE Approval to Initiate Pivotal Investigation of the Angel® Catheter

SAN ANTONIO, Jan. 8, 2015 /PR Newswire/ -- BiO2 Medical announces approval of an IDE to initiate a clinical investigation of the Angel® Catheter for Pulmonary Embolism (PE) protection. The study, entitled The Angel® Catheter Clinical Trial: Prevention of Pulmonary Embolism in High Risk Subjects, will build on the positive results of a European Registry and a U.S. Feasibility Study and is expected to begin to enroll subjects in Q1 2015.

The upcoming Angel® Catheter trial is a multicenter, prospective, single arm clinical investigation expected to enroll up to 182 subjects in up to 30 U.S. investigational sites. The primary objective of the study is to evaluate the safety and effectiveness of the Angel® Catheter in subjects at high risk of PE, and with recognized contraindications to standard pharmacological therapy. At the successful completion of the study, BiO2 Medical will be seeking a prophylactic indication, the first for an Inferior Vena Cava (IVC) Filter.

"The Pivotal Clinical Trial is the culmination of years of investigation in this clinical device. The results of this trial will also provide the important clinical data to understand the prophylactic role of this IVC filter and catheter combination. Dr. Victor Tapson, a well-recognized expert in the area of Pulmonary Embolism is the Principal Investigator for this trial, in association with a large group of trauma and critical care physicians who feel that positive results of this trial will provide a substantial contribution in the prevention of significant Pulmonary Embolism events that are associated with increased morbidity and mortality," stated Dr. Luis Angel, BiO2 Medical's President & Chief Medical Officer.

The Angel® Catheter features the rapid and acute protection of a retrievable Nitinol IVC Filter permanently attached to a multi-lumen Central Venous Catheter, which simultaneously provides PE prophylaxis and central venous access for patients at high risk of PE, a large and currently underserved group of patients. The novel design of the Angel® Catheter allows for placement directly at the patient's bedside without the need for fluoroscopy and significantly reduces the complications of traditional IVC filters by ensuring 100% removal of the IVC filter when the catheter is retrieved. Based on the expected prophylactic and temporary capabilities of the device, the wide range of underserved patients including trauma, critical care, and neuro patients, and the absence of direct competition, PE prophylaxis using the Angel® Catheter presents a potentially lucrative market opportunity.

BiO2 Medical, Inc. is a Texas based medical device manufacturer with corporate offices in San Antonio, Texas, and R&D and manufacturing operations in Golden, Colorado. For more information on The Angel® Catheter Clinical Trial, please visit clinicaltrials.gov (NCT02186223). Inquiries regarding the study should be directed to Dr. Margaret Tumas, BiO2 Medical's VP of Clinical Affairs, at mtumas@bio2medical.com.

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