# Pivotal Investigation of BiO2 Medical's Angel Catheter Exceeds Enrollment Expectations

GOLDEN, Colo., May 19, 2015 /PRNewswire/ -- BiO2 Medical is pleased to announce The Angel® Catheter Clinical Trial is off to an exceptional start with subject enrollment already greater than 25% within the first 3 months of the study start-up. As of this writing, 40 evaluable subjects, of the targeted 150, have successfully been enrolled in the study.

Enrollment for The Angel® Catheter Clinical Trial began in February and there are currently 13 sites actively enrolling subjects for this prospective, single arm clinical investigation of the Angel® Catheter. Principal Investigator enthusiasm coupled with enrolled subjects consisting of a diverse patient population led primarily by trauma patients, has contributed to positive enrollment figures.

Dr. Julie Dunn, Principal Investigator at University of Colorado Health, in Loveland, Colorado, commented, "This represents novel technology important for use in patients with high risk of VTE who cannot tolerate anticoagulation due to the spectrum of their injuries. The device has been easy to place and deploy. We have seen the greatest utility in patients with severe head and spinal cord injuries. No one knows the true incidence of early DVT, but we have already had a patient with a popliteal DVT due to lower extremity injuries in addition to a traumatic brain injury. It was comforting to know we had him protected."

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 Pulmonary Embolism (PE) protection 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. At the successful completion of the study, BiO2 Medical will be seeking a prophylactic indication, the first for an Inferior Vena Cava (IVC) filter.

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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