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AngioDynamics Earns FDA Clearance for Ports With BioFlo Technology to Reduce Catheter-Related Thrombus

ALBANY, N.Y., Aug. 20, 2013 (GLOBE NEWSWIRE) -- AngioDynamics (Nasdaq:ANGO), a leading provider of innovative, minimally invasive medical devices for vascular access, surgery, peripheral vascular disease and oncology, announced the U.S. Food and Drug Administration has granted 510(k) clearance to Navilyst Medical Inc., an AngioDynamics company, for its BioFlo Port with Endexo technology designed to reduce the accumulation of catheter-related thrombus on, and in, the port catheter. This marks the second U.S. clearance of a product line developed with BioFlo's advanced technology; an initial launch is expected in the Company's third quarter of fiscal year 2014.

Implantable ports are medical devices implanted under the skin that facilitate long-term delivery of medication and access to a patient's vascular system for repeated intravenous treatments such as chemotherapy, blood withdrawal or delivery of total parenteral nutrition. Medical device thrombosis caused by products such as ports costs the U.S. healthcare system an estimated $1 billion annually with over 50,000 deaths per year caused by thromboembolism and cancer patients among those most susceptible to thrombosis.

The BioFlo Port is the only port manufactured with Endexo technology, a permanent and non-eluting integral polymer, designed to provide more resistance to the accumulation of platelets and thrombus.[1]

"We're pleased to build on the success of our BioFlo PICC by introducing the first port with a demonstrated reduction in thrombus accumulation[1,2]," said Joseph M. DeVivo, President and CEO of AngioDynamics. "The introduction of BioFlo ports is consistent with our plan to bring disruptive technologies into the Vascular Access space and reflects the strengthening of our BioFlo platform."

BioFlo technology shows promise in decreasing the accumulation of catheter-related thrombus without incorporation of heparin, antibiotics or antimicrobials, or any other transient materials typically associated with coated or impregnated technologies. In-vitro blood loop model test results show that on average the BioFlo Port catheter had 96% less thrombus accumulation on its surface compared to non-coated conventional port catheters (based on platelet count).[2] The BioFlo Ports are also available with PASV Valve Technology, AngioDynamics' patented valve designed to automatically resist backflow and reduce blood reflux on the inside of the catheter.

"We're pleased to have received BioFlo Port clearance ahead of our expected schedule and plan to launch BioFlo ports during the third fiscal quarter of 2014, bringing a financial impact to the second half of FY14." said Chuck Greiner, Vice President of the Global Vascular Access Franchise. "Given the strong performance we continue to see in BioFlo PICCs since our worldwide launch, we are excited to expand this premium technology into other segments. We will continue to grow our BioFlo vascular access portfolio by seeking FDA clearance for BioFlo dialysis catheters."

[1]The reduction in thrombus accumulation was evaluated using in-vitro and in-vivo models. Pre-clinical in-vitro and in-vivo evaluations do not necessarily predict clinical performance with respect to thrombus formation.

[2]Based on benchtop test results which may not be indicative of clinical results. Data on file.

About AngioDynamics

AngioDynamics Inc. is a leading provider of innovative, minimally invasive medical devices used by professional healthcare providers for vascular access, surgery, peripheral vascular disease and oncology. AngioDynamics' diverse product lines include market-leading ablation systems, fluid management systems, vascular access products, angiographic products and accessories, angioplasty products, drainage products, thrombolytic products and venous products. More information is available at www.AngioDynamics.com.

Trademarks

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