Vasorum Ltd. Receives FDA Approval for Celt ACD® Vascular Closure Device

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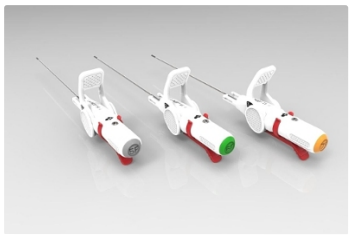

DUBLIN, July 21, 2016 /PRNewswire/ --

Vasorum Ltd. The developer and manufacturer of the novel Celt ACD® vascular closure device has received approval of its PMA application from the US Food and Drug Administration (FDA). Celt ACD®, which previously received CE mark and is sold in Europe, is indicated for arterial puncture closure in both diagnostic and anticoagulated percutaneous interventional cardiology and radiology patients. Celt ACD® offers excellent time to hemostasis in a wide variety of clinical situations. A randomized controlled clinical trial which recruited 207 interventional cardiology procedure patients was carried out in four International Cardiology Centres across US and Europe. The trial's Principal Investigator was Dr. Shing-Chiu Wong, Director of Cardiac Catheterization at the NewYork-Presbyterian/Weill Cornell Medical Center. Dr Wong commented that he "was very pleased with the positive outcome of the clinical trial which shows that Celt ACD® can help in addressing the clear need for quicker and more efficient methods of increasing patient throughput in healthcare facilities."

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There are currently over 8 million catheter procedures performed annually, which support an estimated $1bn femoral artery closure device market. The number of procedures is expected to exceed 10 million by 2020. In addition to interventional cardiology procedures, the market growth is being driven by an increasing number of peripheral vascular, neuro-vascular and other catheter procedures which demand more patient friendly devices and more efficient patient discharge from hospitals. Given its ease of use and wide clinical applicability, Celt ACD® is well positioned to address this broad and growing market opportunity.

"With more than 20,000 patient implants to date in Europe, Celt ACD® has proven itself to be a best in class arterial puncture closure device. Celt ACD® allows immediate closure of multiple re-sticks in calcified vessels and is also very comfortable for patients. The FDA approval is a very significant milestone allowing US market entry by Vasorum," stated James Coleman MD, co-founder and CEO of Vasorum.

About Vasorum

Vasorum Ltd. is an Irish medical device research and development company supported by Enterprise Ireland that has developed Celt ACD®, a single use femoral artery puncture closure device in three sizes for safe and effective closure of 5F, 6F and 7F punctures. Celt ACD® was designed to be more clinically versatile than other devices by allowing physicians to carry out multiple re-stick procedures and addressing a broader range of clinical situations and patient anatomies. Furthermore the device was designed to help achieve more efficient workflow in the cath lab, by achieving rapid and definitive closure and allowing for earlier ambulation of the patient. Celt ACD® is currently being used in Europe by cardiologists, radiologists, angiologists and endovascular surgeons with excellent clinical feedback. The technology pipeline includes the development of Celt ACD® to close 12-14F punctures. The company anticipates launch of Celt ACD® in the US market place in Q3 2016.

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