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Medtronic enrolls first patient in Onyx™ Liquid Embolic IDE Clinical Study for embolization of arterial hemorrhage in peripheral vasculature

Albany Medical Center performs first patient procedure in clinical trial for use of peripheral vasculature liquid embolization for active arterial hemorrhage

Medtronic, a global leader in healthcare technology, today announced that the first patient has been enrolled in the **PE**ripheral Onyx™ **L**iquid **E**mbolic (PELE) clinical trial, which will evaluate the safety and effectiveness of the Onyx™ Liquid Embolic System (LES) for embolization of arterial hemorrhage in the peripheral vasculature. The first procedure was performed by Dr. Christopher Stark at Albany Medical Center.

Data from the PELE IDE Clinical Study is intended to evaluate the safety and effectiveness of Onyx LES in the treatment of subjects with active arterial bleeding in the peripheral vasculature that are deemed suitable for embolization treatment. In this study, peripheral vasculature is defined as outside of the brain and heart.

"Embolic agents are an important tool to address hemorrhage. In this case, the patient experienced bleeding due to a ruptured blood vessel following a routine medical procedure. Onyx LES was administered into the target vessel to successfully facilitate embolization," said Chistopher Stark, M.D., vascular and interventional radiologist at Albany Medical Center. "Albany Medical Center is proud to be enrolling patients in the PELE IDE Clinical Study, the aim of which is to gather evidence to support the safety and efficacy of Onyx LES in treatment of peripheral arterial hemorrhage."

This pivotal, prospective, multi-center, non-randomized, single arm study will enroll up to 119 patients from up to 25 sites in the U.S. The primary safety and efficacy endpoints will be evaluated through 30 days following treatment with Onyx LES.

"Onyx LES is available with a peripheral indication in many markets outside the U.S.," said David Moeller, president of the Peripheral Vascular Health business, which is part of the Cardiovascular Portfolio at Medtronic. "This trial will generate the evidence necessary for U.S. physicians to use Onyx for embolization of arterial hemorrhage in the peripheral vasculature, a key part of advancing our embolic portfolio strategy."

The PELE IDE Clinical Study will build upon extensive commercial experience from the use of Onyx LES in the peripheral vasculature globally. It aims to provide the necessary evidence to add Onyx LES to the U.S. portfolio of

peripheral vasculature embolization products from Medtronic. In the United States, the use of Onyx LES for embolization of arterial hemorrhage in the peripheral vasculature is investigational and has not been approved or cleared by the U.S. Food and Drug Administration.

About Medtronic

Bold thinking. Bolder actions. We are Medtronic. Medtronic plc, headquartered in Galway, Ireland, is the leading global healthcare technology company that boldly attacks the most challenging health problems facing humanity by searching out and finding solutions. Our Mission — to alleviate pain, restore health, and extend life — unites a global team of 95,000+ passionate people across more than 150 countries. Our technologies and therapies treat 70 health conditions and include cardiac devices, surgical robotics, insulin pumps, surgical tools, patient monitoring systems, and more. Powered by our diverse knowledge, insatiable curiosity, and desire to help all those who need it, we deliver innovative technologies that transform the lives of two people every second, every hour, every day. Expect more from us as we empower insight-driven care, experiences that put people first, and better outcomes for our world. In everything we do, we are engineering the extraordinary. For more information on Medtronic, visit www.Medtronic.com and follow on LinkedIn.

Any forward-looking statements are subject to risks and uncertainties such as those described in Medtronic's periodic reports on file with the Securities and Exchange Commission. Actual results may differ materially from anticipated results.

Contacts:
Laura Hennen
Public Relations
+1-763-213-3034

Ryan Weispfenning
Investor Relations
+1-763-505-4626

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