Medtronic News

Medtronic Announces One-Month DAPT Clinical Study in the U.S. and Japan with Resolute Onyx DES in High Bleeding Risk Patients

(GLOBE NEWSWIRE via COMTEX) --The Onyx ONE Clear Study Builds Upon Body of Clinical Evidence to Inform Individualized DAPT Duration Following Stent Procedures

DUBLIN - September 10, 2018 - Medtronic plc (NYSE:MDT) today announced the start of the Onyx ONE Clear Study in the U.S. and Japan that will evaluate one-month dual antiplatelet therapy (DAPT) in high bleeding risk patients implanted with the Resolute Onyx(TM) Drug-Eluting Stent (DES) during percutaneous coronary intervention (PCI).1 The Onyx ONE Clear Study is one of the first studies in the U.S. and Japan designed to investigate safety - such as risk of cardiac death, heart attack and stent thrombosis - following DAPT interruption or discontinuation at one month with a next generation DES.

"One-month DAPT duration after coronary stenting in high bleeding risk patients offers the potential to substantially enhance the safety of interventional procedures in these high-risk patients," said Gregg W. Stone, M.D., professor of medicine at Columbia University in New York, and program chair of the Onyx ONE Month DAPT Program. "This study will provide insight as to whether one-month DAPT after Resolute Onyx in high bleeding risk patients is effective in minimizing stent thrombosis and other complications, thereby reducing bleeding-related harm with prolonged anti-platelet therapy."

Designed similarly to the randomized Onyx ONE Global Study, which began enrollment in late 2017, the Onyx ONE Clear Study will assess patients prescribed one month of DAPT, the combination of aspirin and an anti-clotting medication, following PCI with the Resolute Onyx DES. Onyx ONE Clear Study and the Onyx ONE Global Study make up the Medtronic Onyx ONE Month DAPT Program that will enroll approximately 2,700 patients at up to 140 sites worldwide.

"As newer-generation DES have not only grown more and more efficacious, but also have demonstrated excellent safety, a major clinical question that remains is whether we can further reduce the mandatory duration of dual antiplatelet therapy after DES implantation," said Ajay Kirtane, M.D., director, New York-Presbyterian Hospital/Columbia University Cardiac Catheterization Laboratories, associate professor of medicine at Columbia University. "The Onyx One Clear study will provide important insights applicable to many patients - both patients identified at high risk of bleeding, as well as those in whom unexpected bleeding events may occur."

To date, more than 20,000 patients have been studied in Medtronic clinical trials that have addressed DAPT duration. The Resolute Onyx DES received CE (Conformité Européene) Mark in September 2014 and FDA approval in April 2017.

"This large-scale clinical study will help address an unmet need as high bleeding risk patients have been largely underrepresented in previous studies looking at shorter DAPT duration," added David Kandzari, M.D., director of interventional cardiology and chief scientific officer, Piedmont Heart Institute in Atlanta, Ga., and co-principal investigator in the study.

In collaboration with leading clinicians, researchers, and scientists worldwide, Medtronic offers the broadest range of innovative medical technology for the interventional and surgical treatment of cardiovascular disease and cardiac arrhythmias. The company strives to offer products and services that deliver clinical and economic value to healthcare consumers and providers around the world.

About Medtronic

Medtronic plc (www.medtronic.com), headquartered in Dublin, Ireland, is among the world's largest medical technology, services and solutions companies - alleviating pain, restoring health and extending life for millions of people around the world. Medtronic employs more than 86,000 people worldwide, serving physicians, hospitals and patients in more than 150 countries.

The company is focused on collaborating with stakeholders around the world to take healthcare Further, Together.

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.

-end-

1 The Onyx ONE Clear Study will also include patients medically unsuitable for more than one-month DAPT treatment.

Contacts:
Joey Lomicky
Public Relations
+1-763-526-2494

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

This announcement is distributed by Nasdaq Corporate Solutions on behalf of Nasdaq Corporate Solutions clients.

The issuer of this announcement warrants that they are solely responsible for the content, accuracy and originality of the information contained therein.

Source: Medtronic plc via Globenewswire

---

https://news.medtronic.com/2018-09-10-Medtronic-Announces-One-Month-DAPT-Clinical-Study-in-the-U-S-and-Japan-with-Resolute-Onyx-DES-in-High-Bleeding-Risk-Patients