Medtronic News

Medtronic receives FDA approval for latest generation drug-eluting coronary stent system

The Onyx Frontier™ drug-eluting stent offers an innovative delivery system and builds upon the acute performance and clinical data from the Resolute Onyx™ drug-eluting stent

DUBLIN, May 13, 2022 /PRNewswire/ -- Medtronic plc (NYSE:MDT), a global leader in healthcare technology, today announced it received U.S. Food and Drug Administration (FDA) approval for the Onyx Frontier™ drug-eluting stent (DES). As the latest evolution in the Resolute DES family, Onyx Frontier DES leverages the same best-in-class stent platform as Resolute Onyx™ DES, with an enhanced delivery system[1] designed to improve deliverability and increase acute performance[2] in even the most challenging of cases.[1]

The Onyx Frontier DES is used for the treatment of patients with coronary artery disease (CAD), which is caused by plaque buildup on the inside of the coronary arteries. These plaque deposits can narrow or clog the inside of the arteries, which decreases the supply of blood and oxygen to the heart. CAD is the leading cause of death for both men and women in the United States.[3] To help to restore blood flow, a physician may use a stent (a flexible metal scaffolding) that is delivered during a minimally invasive procedure to prop open the artery. A drug-eluting stent is the most common type of stent used to treat a blockage of the heart arteries.[4]

"The new Onyx Frontier DES, with its enhanced deliverability, will continue to help interventional cardiologists treat complex coronary cases and larger ranges of vessel sizes more efficiently," said Azeem Latib, M.D., section head of interventional cardiology and medical director of structural heart interventions at Montefiore Medical Center in New York City. "Delivering safe and effective outcomes to our patients is our number one priority. It's important that physicians have access to tools like the Onyx Frontier DES that can allow them to efficiently achieve those outcomes."

Meaningful design changes, including increased catheter flexibility, an innovative dual-layer balloon technology and a lower crossing profile led to a 16% improvement in deliverability with Onyx Frontier vs. the previous generation Resolute Onyx DES.[2] In addition to the delivery system enhancements, Onyx Frontier offers a broad size matrix to treat more patients and is the only 2.0 mm DES available in the United States (similar to Resolute Onyx). Further, Onyx Frontier continues to provide 4.50-5.00 mm sizes that can be expanded to 6.00 mm - specifically designed to support extra-large vessels. Onyx Frontier shares the same clinical indications as Resolute Onyx, including the most recent approval for patients that are at high risk of bleeding who may benefit from a dual antiplatelet therapy (DAPT) duration as short as one month.[2]

"The Onyx Frontier DES FDA approval is a very important milestone for Medtronic's Coronary business and demonstrates our commitment to interventional cardiologists by providing best-in-class products," said Jason Weidman, senior vice president and president of the Coronary & Renal Denervation business, which is part of the Cardiovascular Portfolio at Medtronic. "The Onyx Frontier launch also correlates directly to Medtronic's commitment to engineering. The team built upon the design and clinical successes of the Resolute Onyx DES and has continued to evolve proven DES technology to further address the needs of physicians. We look forward to continuing the pursuit of innovation each day."

The Onyx Frontier DES is now approved in the United States and is pending CE (*Conformité Européene*) Mark.

About Medtronic

Bold thinking. Bolder actions. We are Medtronic. Medtronic plc, headquartered in Dublin, 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 90,000+ passionate people across 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 (NYSE:MDT), visit www.Medtronic.com and follow @Medtronic on Twitter and 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.

[1] Stent delivery system updates were implemented on the 2.0–4.0 mm Onyx Frontier DES diameters.

[2] Bench test data on file at Medtronic. May not be indicative of clinical results.

[3] National Heart, Lung and Blood Institute

[4] Mayo Clinic Staff. Drug-Eluting Stents: Do they increase heart attack risk? Mayoclinic.org

Contacts:

Lauren Elizabeth Mueller	Ryan Weispfenning
Public Relations	Investor Relations
+1-763-285-9053	+1-763-505-4626

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