Medtronic News

CORRECTING and REPLACING Medtronic IN.PACT Drug-Eluting Balloon Studies Show Significant Benefit of Novel Medical Device in Treating Narrowed Arteries

Randomized Controlled Trial Results Presented At EuroPCR Demonstrate Advantages Over Uncoated Angioplasty Balloons and Drug-Eluting Stents

PARIS--(BUSINESS WIRE)--May. 16, 2012-- Please replace the release with the following corrected version due to multiple revisions.

The corrected release reads:

MEDTRONIC IN.PACT DRUG-ELUTING BALLOON STUDIES SHOW SIGNIFICANT BENEFIT OF NOVEL MEDICAL DEVICE IN TREATING NARROWED ARTERIES

Randomized Controlled Trial Results Presented At EuroPCR Demonstrate Advantages Over Uncoated Angioplasty Balloons and Drug-Eluting Stents

Adding to the growing body of evidence on a novel interventional cardiovascular device, physicians presented today at EuroPCR 2012 the results of two multicenter, randomized controlled trials, the BELLO and PACIFIER studies, each one showing statistically significant advantages of using an IN.PACT drug-eluting balloon from Medtronic, Inc. (NYSE: MDT) over a corresponding conventional treatment for coronary and peripheral artery disease, respectively.

Medtronic IN.PACT drug-eluting balloons received CE (Conformité Européenne) mark in 2008 and 2009 and are available in many countries around the world. They are not commercially available in the United States.

BELLO

The physician-initiated BELLO (Balloon Elution and Late Loss Optimization) study enrolled 182 patients across 15 hospitals in Italy to evaluate the Medtronic IN.PACT Falcon™ drug-eluting balloon versus the Taxus drug-eluting stent (DES) from Boston Scientific Corp. for safety and effectiveness in reducing late lumen loss in small-vessel coronary artery disease.

With both devices eluting paclitaxel, the late lumen loss (LLL) rate associated with the IN.PACT Falcon drug-eluting balloon (0.09 mm ± 0.38 mm) was superior to the Taxus DES (0.30 mm ± 0.44 mm) on the primary endpoint of in-stent/in-balloon LLL at six months (p=0.001).

“The results of the BELLO study show that Medtronic’s IN.PACT Falcon drug-eluting balloon may be a viable alternative to drug-eluting stents in treating small coronary vessels that have narrowed due to atherosclerosis, in addition to vessels with in-stent restenosis,” explained Dr. Antonio Colombo of Ospedale San Raffaele in Milan, co-principal investigator and presenter of the BELLO study. “Encouragingly, the angiographic findings of the independent core lab are concordant with the clinical results.”

In addition, rates of major adverse cardiac events (MACE) between the two groups were similar at six months:

- MACE – IN.PACT Falcon DEB 10.0%, Taxus DES 16.3%
- death – IN.PACT Falcon DEB 1.1%, Taxus DES 1.1%
- myocardial infarction (MI) – IN.PACT Falcon DEB 1.1%, Taxus DES 5.5%
- target lesion revascularization (TLR) – IN.PACT Falcon DEB 4.4%, Taxus DES 7.7%
- target vessel revascularization (TVR) – IN.PACT Falcon DEB 7.8%, Taxus DES 11.0%

Importantly for assessing the results, nearly two-thirds (64.9%) of the vessels treated in the BELLO study with Medtronic’s IN.PACT Falcon DEB were smaller than 2.25 mm in diameter, for which no DES is currently available.

PACIFIER

The PACIFIER (Paclitaxel-coated Balloons in Femoral Indication to Defeat Restenosis) study enrolled 91 patients across three hospitals in Germany. The one-year results demonstrated a statistically significant advantage in preventing the superficial femoral artery (SFA) from renarrowing when using the Medtronic IN.PACT Pacific™ drug-eluting balloon versus conventional, uncoated balloons.

On the primary endpoint results of LLL at six months, there was a statistically significant difference (p = 0.0014) and exceedingly low rate (-0.01mm) of LLL associated with the use of Medtronic's IN.PACT Pacific drug-eluting balloon compared to patients treated with an uncoated balloon (0.65mm). PACIFIER also significantly favored the IN.PACT Pacific drug-eluting balloon on a composite of death, amputation, and the need for target lesion revascularization (TLR) at one year (7.1% versus 34.9%, p=0.002).

"While preliminary drug-eluting balloon data from uncontrolled trials have been promising, the interventional community has eagerly awaited the results from a randomized trial to validate the clinical benefit of Medtronic's IN.PACT drug-eluting balloons," commented Michael Werk, M.D., assistant medical director for the Department of Radiology at the Martin Luther Hospital in Berlin and PI and presenter of the PACIFIER trial. "Earlier research has hypothesized that drug-eluting balloons can reduce late lumen loss, restenosis rates and the need for repeat target lesion revascularization, and now the one-year results of PACIFIER show, in a randomized forum, to what extent these results are possible."

Ultimately, Medtronic's global IN.PACT clinical program will include 24 studies involving approximately 4,000 patients and 200 sites across more than 80 countries worldwide. Through these company-sponsored and physician-initiated studies, Medtronic IN.PACT drug-eluting balloons will be investigated thoroughly for the treatment of arterial disease in coronary and peripheral vessel beds.

Last month, for example, Medtronic announced the start of the IN.PACT Global SFA clinical study, an international research program to evaluate the treatment of peripheral artery disease using the company's IN.PACT Admiral™ drug-eluting balloon in up to 1,500 "real world" patients. The first patient in the study is expected to be enrolled by the end of May.

In collaboration with leading clinicians, researchers and scientists, 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 worldwide.

ABOUT MEDTRONIC

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