Medtronic News

Medtronic Resolute(R) Drug-Eluting Stent Exhibits Strong Safety Profile in Broad Spectrum of Patients

Late-breaker at EuroPCR Confirms Low Rates of Adverse Events with Novel Heart Device in More Than 5,000 Study Subjects

PARIS, May 20, 2011 (BUSINESS WIRE) --

A pooled analysis of the global RESOLUTE clinical program presented today during a late-breaking clinical trials session at EuroPCR demonstrated the strong safety record of the Resolute drug-eluting stent (DES) from Medtronic, Inc. (NYSE: MDT), across a wide variety of patient and lesion types.

Dr. Laura Mauri, an interventional cardiologist at Brigham and Women's Hospital and chief scientific officer of the Harvard Clinical Research Institute in Boston, presented two-year safety data on 5,130 patients who received a Resolute DES by participating in one of five Medtronic-sponsored studies of this novel implantable heart device:

- RESOLUTE first-in-man feasibility study (n=139)
- RESOLUTE All Comers (n=1,140)
- RESOLUTE International (n=2,349)
- RESOLUTE US (n=1,402)
- RESOLUTE Japan (n=100)

The results of this analysis, called RESOLUTE Pooled Safety, were compared to those of RESOLUTE All Comers (R-AC) subjects who received a Xience V DES (n=1,152) from Abbott Laboratories and also to those of ENDEAVOR II (E-II) subjects who received a Driver bare-metal stent (n=596) from Medtronic. R-AC and E-II are both Medtronic-sponsored randomized controlled trials.

As summarized in the tables below, Dr. Mauri showed comparative data on the following endpoints through two years:

- target lesion failure (TLF), a composite of cardiac death (CD), target vessel myocardial infarction (TVMI) and clinically driven target lesion revascularization (TLR)
- clinically driven TLR
- CD / TVMI
- definite/probable stent thrombosis (def/prob ST)

RESOLUTE Pooled Safety: Two-Year Outcomes (All Patients)

	Resolute DES	*Xience V DES*
Endpoint	(n=5,130)	(n=1,152)
TLF	9.5%	10.7%
CD / TVMI	5.4%	6.2%
clinically driven TLR	5.0%	5.2%
def/prob ST	1.0%	1.0%

RESOLUTE Pooled Safety: Two-Year Outcomes (On-Label / Single-Lesion Subset)

	Resolute DES	*Driver BMS*
Endpoint	(n=2,466)	(n=596)
TLF*	7.8%	17.6%
CD / TVMI	4.3%	5.8%

clinically driven TLR**	3.8%	14.2%
def/prob ST***	0.3%	1.3%

* TLF: adjusted p = <0.0001 ** TLR: adjusted p = <0.0001 *** def/prob ST: adjusted p = 0.0125

None of the differences on these endpoints are statistically significant, unless otherwise noted.

"Our analysis shows that the Resolute DES performed at least as well as another contemporary drug-eluting stent and better than a similarly designed bare-metal stent on clinically meaningful safety endpoints through two-years of patient follow-up," Dr. Mauri concluded. "It also supports a broader point: that while bare-metal stents have previously served as the gold standard for safety and drug-eluting stents for efficacy, evolving DES designs - like those embodied by Medtronic's Resolute system - set a new standard for both parameters."

RESOLUTE Pooled Safety adds depth to previous characterizations of the Resolute DES. It led the EuroPCR session titled "Late-Breaking Registries and Trial Updates" and marks the first time that multiple data sets from the RESOLUTE clinical program were ever presented in their totality and in context. The available data on the Resolute DES has grown exponentially over the last year, as outcomes to at least one year for more that 5,000 patients involved in the program have become available.

The Resolute DES is commercially available in more than 100 countries outside the United States. In the U.S., Resolute DES is currently limited to investigational use, it is being evaluated in a clinical trial approved by the U.S. Food and Drug Administration (FDA). The global RESOLUTE clinical program is a collaborative effort involving hundreds of medical centers in more than 25 countries across Europe, Asia, the Pacific Rim, the Middle East, Africa, Latin America and North America.

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.

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