Two-Year Feasibility Study Results Encouraging with Medtronic Harmony(TM) Transcatheter Pulmonary Valve

April 26, 2018 12:00 PM CT

Medtronic

DUBLIN and SAN DIEGO - April 26, 2018 - Medtronic plc (NYSE: MDT) today announced two-year outcomes for the Harmony(TM) Transcatheter Pulmonary Valve (TPV) from its early feasibility study. Presented at the Society for Cardiovascular Angiography and Interventions (SCAI) 41st Annual Scientific Sessions, data from 18 patients followed out to two years revealed the Harmony TPV showed solid valve function and no paravalvular leak (PVL).

"Following the one-year feasibility outcomes, we are encouraged to see the Harmony valve continues to show positive outcomes for patients two years post-implant," said Matthew J. Gillespie, M.D., cardiologist at The Cardiac Center at Children's Hospital of Philadelphia, who presented the data at the meeting. "We are optimistic that these early outcomes will be a strong indicator of the types of results that we might expect to see from our pivotal study, which is currently enrolling."

Designed to offer a treatment alternative for patients with Congenital Heart Disease (CHD), the Harmony TPV is being studied in CHD patients born with right ventricular outflow tract (RVOT) anomalies who undergo a surgical repair early in life. For these patients, who account for approximately 80 percent of CHD patients born with RVOT anomalies, the Harmony TPV provides a less invasive option to help restore normal valve function later in life.

Consistent with one-year outcomes presented at TCT16, patients enrolled in the Harmony TPV early feasibility study who have now been followed out to two years (N=18) continued to experience strong hemodynamics (blood flow), with 86.7 percent of patients having no/trace pulmonary regurgitation (PR) at two years. Mean gradients were consistent and stable at two years follow up and there were no paravalvular leaks reported. Two patients experienced tissue growth within the stent frame and were treated successfully with a transcatheter valve-in-valve procedure with the Melody(TM) TPV.

"It's important that these patients have access to a less invasive non-surgical option, and the Harmony TPV is uniquely designed to adapt to a wide variety of patient anatomies," said Pieter Kappetein, M.D., Ph.D., vice president and chief medical officer of the Structural Heart business, which is part of the Cardiac and Vascular Group at Medtronic. "Medtronic remains committed to congenital heart disease and we continue to look for ways to expand therapeutic options and improve outcomes for these patients, from their first surgeries as young children through their years as active, high-functioning adults."

The Harmony TPV is available for investigational use only. Harmony Pivotal IDE Study is treating up to 40 patients at approximately 15 sites in the U.S., Canada, and Japan. Medtronic has a long-standing commitment to congenital heart disease and introduced the first transcatheter heart valve available anywhere in the world in 2006 - the Melody TPV - which has been implanted in more than 12,000 patients worldwide.

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 84,000 people worldwide, serving physicians, hospitals and patients in more than 160 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-

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

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