### Key Medtronic Heart Failure Research Trials

#### Delivery for Pulmonary Arterial Hypertension (PAH)

**Primary Investigator**
Robert C. Bourge, MD, University of Alabama at Birmingham

**Background**
Pulmonary arterial hypertension (PAH) is a rare and devastating disease characterized by high blood pressure in the arteries leading to the lungs that ultimately results in right heart failure and premature death. Current external systems for parental administration of prostanoids (vasodilators) expose patients to risk of infection, catheter complications, and interference with activities of daily living. A fully implantable system for long-term intravenous infusion of Remodulin® injection will be evaluated for safety.

**Primary Objective**
To demonstrate that the Model 10642 Implantable Intravascular Catheter is safe when used with the Medtronic SynchroMed® II Implantable Infusion System to deliver Remodulin Injection. The end point is catheter-related complications per 1,000 patient days.

**Methods**
- Multicenter, prospective, single arm, non-randomized, open label
- Up to 70 subjects at up to 10 US sites, followed for at least 12 months
- Patients currently treated with the approved intravenous (IV) infusion route of delivery of Remodulin Injection

**Status**
- Currently in follow-up
- Study start: June 2011
- Estimated completion: Fall 2015

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**Funding**
United Therapeutics Corporation

**ClinicalTrials.gov ID:** NCT01213251

#### PROMPT

**Primary Investigator**
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**Background**
An estimated 785,000 patients will experience a new acute MI and 470,000 will have a recurrent MI in the United States in 2011, resulting in potential healthcare costs to $177.5 billion. Within 5 years of an index MI, the risk of developing heart failure (HF) has been reported to range up to 31%. A novel pacing approach that prevents paroxysmal ventricular tachycardia may aid in preventing the development of HF following an MI.

**Primary Objective**
To demonstrate the feasibility of post-MI LV or BV pacing to prevent adverse cardiac remodeling as assessed by LVEF at 18 months.

**Methods**
- Prospective, randomized 1:1:1 (BiV pacing vs. LV pacing vs. Control), partially blinded
- Up to 250 subjects at 30 centers (US, Europe, Asia, Middle East), followed to 18 months
- Subjects with first time MI < 10 days, peak CPK > 3,000 μ/L (or TnT > 10 μ/L)

**Status**
- Currently recruiting patients
- Study start: December 2010
- Estimated completion: April 2015

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**Funding**
Medtronic, Inc.

**ClinicalTrials.gov ID:** NCT01112579

#### DEFEAT-HF

**Primary Investigator**
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**Background**
Autonomic nervous system dysfunction is a key pathophysiology of heart failure and sudden cardiac death. Improving autonomic balance to favor the parasympathetic nervous system has been attempted to improve symptoms and manifestations of HF. Current evidence suggests that thoracic spinal cord stimulation (SCS) may improve heart failure symptoms and decrease sinus rate and AV prolongation.

**Primary Objective**
To evaluate the reduction in left ventricular and systolic volume index ($\Delta ESVi$) after 6 months of SCS therapy.

**Methods**
- Prospective, randomized 3:2 (SCS vs. Control), parallel controlled study
- Up to 250 subjects enrolled at 30 centers (North America, Europe), followed to ≥ 12 months
- Subjects with EF ≤ 35%, NYHA III, QRS ≤ 120 ms, ICD indication

**Status**
- Follow-up phase
- Study start: June 2010
- Estimated completion: July 2014

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**Funding**
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**Notice of Availability**
Catheters, investigational devices. Limited by Federal law (USA) for investigational use.

The intended purpose of the posters is to provide physicians with information about the Delivery for PAH, PROMPT, and DEFEAT-HF studies in an effort to help make a decision about enrolling patients for possible participation in these studies. Medtronic, Inc. is sponsoring the Delivery for PAH, PROMPT, and DEFEAT-HF studies. Note that the devices used in these studies are not generally available to the public for the indications under investigation in this study.