Clinical Trial to Evaluate Pacemaker Safety and Efficacy in MRI Environment: Device and Study Design

E. Kanal[1], T. Sommer[2], D. Bello[3], R. Luenchinger[4], R. Sutton[5], and B. Wilkoff[6]

[1]UPMC Presbyterian, Pittsburgh, PA, United States, [2]University of Bonn, Bonn, Germany, [3]Mid-Florida Cardiology Specialists, Orlando, FL, United States, [4]University Hospital, Zurich, Switzerland, [5]St. Mary's Hospital, London, United Kingdom, [6]Cleveland Clinical Foundation, Cleveland, OH, United States

Rationale: With an estimated 60 million MRI scans performed annually worldwide and up to 75% of pacemaker patients needing an MRI during the life-time of the pacemaker, MRI-pacemaker compatibility is a significant need. A pacemaker system has been designed and pre-clinically tested for MRI compatibility. A trial has started in Europe and Canada as of February 2007.

Device Design: The new pacemaker and leads are designed to minimize lead tip heating and induced energy on leads, which could potentially result in loss of capture and unintended stimulation/arrhythmia. The pacemaker also includes a new feature to eliminate the impact of MRI-generated electrical noise, which can deliver unnecessary pacing therapy, or cause oversensing by the pacemaker and prevent necessary pacing therapy. The data collection and monitoring functions are temporarily suspended, while allowing the pacing system to continue providing asynchronous pacing, if needed. The system contains radiopaques identifiable via X-ray to indicate that the system is MRI-compatible.

In-vivo animal studies indicate that there is no cumulative effect from multiple MRI scans and that any small change in pacing capture threshold (PCT) would occur immediately following an MRI scan. Increases in PCT can be an indication of lead tip heating. To keep radiofrequency (RF) power levels at the lead tip within a moderate range, MRI scans with SAR above 2 W/kg and chest scans are excluded from the trial.

Study Design: The trial will enroll 470 subjects at approximately 75 sites worldwide. Subjects are randomized to receive MRI scans or no MRI scans.

Fifteen clinical relevant head and lumbar MRI sequences were designed, which include sequences with high gradient field exposure and sequences with high RF exposure (SAR up to 2 W/kg). The sequences are applicable on most 1.5 T scanners.

Due to the variability between MRI manufacturers (software levels and hardware), the trial requires that each site validates the sequences to ensure comparable scans between sites.

Primary objectives include MRI-related complications, as well as PCT and sensing changes post-MRI. Data are expected to show that PCT does not change by more than 0.5 V @ 0.5 ms.

Results: As of October 10, 2007, 198 subjects are enrolled and 45 have undergone an MRI scan. To date, no MRI-related complications have been reported.

Conclusion: Preclinical testing of the pacemaker system indicated product compatibility in a controlled MRI environment. The safety and efficacy of the pacemaker system will be evaluated in the ongoing trial.