

EMBARGOED FOR RELEASE UNTIL FRIDAY, MAY 8, 2020, AT 8:00 A.M. EST

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**LATE-BREAKING CLINICAL TRIAL RESULTS ANNOUNCED
AT HRS 2020 SCIENCE:**

**CLINICAL TRIAL REVEALS BENEFITS OF NEW ENERGY SOURCE TO PERFORM ATRIAL
FIBRILLATION ABLATION**

The first-in-human results show pulsed field ablation may deliver safer and more efficient procedures for patients

WASHINGTON, DC, May 8, 2020 — New clinical trial reveals the first-in-human results for paroxysmal or persistent atrial fibrillation (AF) treated with a novel energy source – pulsed field ablation (PFA). The study demonstrates the safety and efficiency benefits of using PFA to target abnormal heart rhythms through pulmonary vein isolation (PVI). Findings of the PULSED AF study were presented today as a late-breaking clinical trial as part of Heart Rhythm Society 2020 Science.

Ablation is a common treatment option for patients with AF, with an estimated 75,000 ablation procedures performed each year in the United States alone.¹ Ablation involves using PVI to ablate, or eliminate the cause of irregular heartbeats. For the past 25 years, the procedure has been performed using thermal energy sources such as radiofrequency (RF) or recent cryoballoon energy. Thermal energy can cause collateral damage to organs and nerves surrounding the heart such as the lungs, esophagus and chest cavity, while pulsed electrical fields target cardiac tissue.

PULSED AF is a non-randomized, prospective, multi-center, global, pre-market clinical study performed in Australia, Canada, United States and Europe. The study evaluates the Medtronic PulseSelect™ system, a PFA system that delivers bipolar, biphasic pulsed electric fields through a circular multi-electrode array catheter to perform PVI. The patients included were undergoing first-time ablation for either paroxysmal or persistent AF (less than one year). The study endpoints include AF recurrence >30 seconds and procedural safety. AF monitoring is being performed by weekly trans-telephonic transmission and intermittent Holters at six and 12 months. Patients will ultimately be followed for 12-months post-ablation.

Results of the PULSED AF study suggest that PFA delivers ablation as effective as RF ablation, while providing a safer and more efficient procedure. Results show acute electrical isolation was achieved in 100 percent of patients to-date and there were no tamponades, strokes or phrenic nerve injuries. Upon conclusion, the study will report the rate of arrhythmia-free survival at 12 months, and pre-specified secondary and ancillary endpoints, including: procedural outcomes, quality of life and arrhythmic symptoms.

“As ablation technology evolves, we saw the opportunity to improve upon the procedure to treat this growing patient population,” said lead author Atul Verma, MD, FHRS, Southlake Regional Health Center, Toronto, ON, Canada. “For the first time, we are able to see positive, in-human

¹ Mansour, M., Karst, E., Heist, E. K., Dalal, N., Wasfy, J. H., Packer, D. L., ... Mahapatra, S. (2017). The Impact of First Procedure Success Rate on the Economics of Atrial Fibrillation Ablation. *JACC: Clinical Electrophysiology*, 3(2), 129–138. doi: 10.1016/j.jacep.2016.06.002

benefits of using a unique, nonthermal energy source to address safety concerns associated with ablation. We look forward to seeing how this technological innovation will move the electrophysiology field forward in advancing this crucial solution and reducing the impact of persisting AF.”

The authors of this study point to a future presentation of full, 12-month patient follow-ups results. This trial will be followed by FDA submission for an international, pivotal trial to provide additional clinical data.

Sessions Details:

“Late-Breaking Clinical Trials II: Innovation Boulevard: *Pulsed AF: First Human Experience and Acute Procedural Outcomes Using A Novel Pulsed Field Ablation System*” [Friday, May 8, 2020 at 11:00 a.m. EST]

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About the Heart Rhythm Society

The Heart Rhythm Society is the international leader in science, education, and advocacy for cardiac arrhythmia professionals and patients and is the primary information resource on heart rhythm disorders. Its mission is to improve the care of patients by promoting research, education, and optimal health care policies and standards. Incorporated in 1979 and based in Washington, D.C., it has a membership of more than 7,000 heart rhythm professionals in more than 70 countries around the world. For more information, visit www.HRSONline.org.