July 26, 2022

Company Name	Otsuka Holdings Co., Ltd.
Name of Representative	Tatsuo Higuchi President and Representative Director, CEO
Code Number	4578, Prime market of the Tokyo Stock Exchange
Contact	Yuji Kogure Director, Investor Relations Department (Phone: +81-3-6361-7411)

Otsuka Medical Devices and ReCor Medical Announce Primary Endpoint Met in the RADIANCE II US Pivotal Trial of the Paradise™ System for the Treatment of Hypertension

Otsuka Medical Devices Co., Ltd., a fully owned subsidiary of Otsuka Holdings Co., Ltd., and ReCor Medical, Inc. ("ReCor") today announced that the RADIANCE II US FDA IDE pivotal trial evaluating the Paradise™ Ultrasound Renal Denervation (uRDN) System as a treatment for hypertension met its primary efficacy endpoint, demonstrating a statistically significant reduction in daytime ambulatory systolic blood pressure between treatment and a sham procedure measured at two months.

The RADIANCE II US FDA IDE pivotal trial is a randomized, sham-controlled clinical trial of the ReCor Paradise uRDN System for the treatment of patients with uncontrolled hypertension. 224 patients with mild-to-moderate uncontrolled hypertension, previously treated with up to two medications, were randomized while off medications at more than 60 study centers in 8 countries.

"Despite the truly formidable challenges of conducting a complex clinical trial in the throes of the COVID-19 pandemic, we are thrilled to observe these positive results of RADIANCE II, especially in light of those we have previously reported from RADIANCE-HTN SOLO and TRIO," said Study Principal Investigators Ajay Kirtane, Professor of Medicine at Columbia University, Vagelos College of Physicians and Surgeons / NewYork-Presbyterian Hospital and Michel Azizi, Professor of Medicine at Université Paris Cité, Hôpital Européen Georges Pompidou, Paris, France. "We cannot adequately convey our thanks to the patients, coordinators, and study physicians for their collective efforts, and we very much look forward to being able to present and publish the complete study details in the near future."

"We at Otsuka are very pleased with the positive outcome of the RADIANCE II study," said Kazumichi Kobayashi, Executive Deputy President of Otsuka Medical Devices. "With three successful clinical trials of the Paradise uRDN System, we believe even more strongly that the Paradise system can become an important treatment option for patients and physicians struggling to control blood pressure."

“ReCor is thrilled that the RADIANCE II pivotal trial met its primary efficacy endpoint. Following the positive SOLO and TRIO clinical trials, RADIANCE II adds to the evidence for the Paradise System as a potential future treatment for patients with uncontrolled hypertension,” said ReCor president and CEO, Andrew M. Weiss. “We would like to express our gratitude to the Principal Investigators, Steering Committee and all investigators for their efforts throughout this important trial.”

RADIANCE II is the third and largest component of ReCor’s RADIANCE Global Program—randomized and sham-controlled studies evaluating the Paradise uRDN System in patients with hypertension. The first two studies in the series are the previously reported RADIANCE-HTN SOLO (conducted in patients with mild-to-moderate hypertension) and TRIO (conducted in those who remained hypertensive despite being on antihypertensive therapy. Both studies met their primary effectiveness endpoints. With RADIANCE II, ReCor now has a third positive trial, with more than 500 patients randomized in the RADIANCE Global Program. ReCor has also begun the Global Paradise System (“GPS”) Registry—a real-world study of up to 3,000 patients with uncontrolled hypertension.

About Otsuka Medical Devices Co., Ltd.
Otsuka Medical Devices focuses on the global development and commercialization of medical care products including endovascular devices that provide new therapeutic options in areas where patient needs cannot be met through pharmaceutical or other conventional treatment. Otsuka Medical Devices Co., Ltd. is a subsidiary of Otsuka Holdings Co., Ltd. (www.otsuka.com/en), a global healthcare company listed on the Tokyo Stock Exchange (JP 4578).
https://www.omd.otsuka.com/en/

About ReCor Medical, Inc.
ReCor Medical, headquartered in Palo Alto, CA, a wholly owned subsidiary of Otsuka Medical Devices Co., Ltd., is a medical technology company focused on transforming the management of hypertension. ReCor has pioneered the use of the Paradise ultrasound renal denervation (uRDN) system for the treatment of hypertension. The Paradise System is an investigational device in the United States and bears the CE mark in the EU. ReCor has reported positive outcomes in three independent, randomized, sham-controlled studies of the Paradise System in patients with mild-to-moderate and resistant hypertension and plans to submit results of its RADIANCE Global Program as part of a PMA to the US FDA for market approval. In addition, ReCor has initiated the Global Paradise System (“GPS”) Registry in the EU with plans to expand on a global basis.
http://www.recormedical.com/