

Otsuka Medical Devices Co., Ltd.
ReCor Medical, Inc.

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Announced Results of Pooled Data Analysis from RADIANCE SOLO and TRIO Studies in Treating Hypertension with the Paradise™ Ultrasound Renal Denervation System

Results presented at EuroPCR 2022 show notable reduction of blood pressure in patients on and off medications at six months

Otsuka Medical Devices Co., Ltd. (“Otsuka Medical Devices”) a fully owned subsidiary of Otsuka Holdings Co., Ltd., and ReCor Medical, Inc. (“ReCor”) today announced that Dr. Ajay Kirtane presented a pooled data analysis from ReCor’s two randomized, sham-controlled trials evaluating the Paradise™ Ultrasound Renal Denervation (uRDN) System for the treatment of hypertension at the EuroPCR annual meeting in Paris. The analysis demonstrated a statistically significant reduction in blood pressure (BP) across a broad range of hypertension severity as represented in the RADIANCE-HTN SOLO and TRIO studies. The data was presented in a late-breaking session titled “Hypertension management in 2022: control it, live longer” on World Hypertension Day.

The pooled analysis combined data from 282 patients randomized in ReCor’s two prospectively powered, sham-controlled studies enrolling two disparate patient populations: TRIO (patients with resistant hypertension) and SOLO (patients with mild-moderate hypertension). There were consistent benefits in both blood pressure reduction and medication burden across the pooled patient population compared to sham. The combined dataset showed an overall between-group difference through 6 months favoring uRDN in daytime ambulatory systolic BP of -4.8 mmHg (95% CI: -7.1 to -2.5, $p < 0.001$) and home systolic BP of -5.4 mmHg (95% CI: -7.3 to -3.6, $p < 0.001$).

“The results of this pooled analysis make clear the consistent blood pressure-lowering effect that ultrasound renal denervation can have across differing severities of hypertension, regardless of trial design and whether the enrolled patients are on or off antihypertensive medications,” said principal investigator Ajay Kirtane, Professor of Medicine at Columbia University, Vagelos College of Physicians and Surgeons and New York-Presbyterian Hospital. “Assuming continued safety of the procedure is demonstrated, ultrasound renal denervation is a promising treatment

option complementary to lifestyle modification and medications for patients with uncontrolled hypertension.”

The RADIANCE Global Program is an international, multicenter, first-of-its-kind initiative designed to explore the benefits of ultrasound renal denervation (uRDN) in hypertension. The RADIANCE studies are double-blind, randomized, sham-controlled trials designed to provide additional information about the ability of the Paradise™ uRDN System to treat high blood pressure. RADIANCE-HTN includes the aforementioned SOLO and TRIO studies, which were individually powered for efficacy with a primary endpoint of daytime systolic ambulatory blood pressure (ABP) at 2 months. Both studies met their primary efficacy and safety endpoints at 2 months.

The RADIANCE Global Program also includes RADIANCE-II, a pivotal trial which recently completed patient enrollment. Study outcomes will be presented to the scientific and medical communities later this year. Results will report on the safety and effectiveness of the Paradise™ uRDN System to reduce blood pressure in patients with hypertension, in the absence of antihypertensive medications.

The Paradise™ uRDN System bears the CE mark for the treatment of hypertension in Europe and is an investigational device in the United States. Hypertension is the leading contributor to disease burden worldwide, leading to increased cardiovascular morbidity and mortality, poorer quality of life, and increased cost to health systems.

About ReCor Medical, Inc.

ReCor Medical, headquartered in Palo Alto, CA, is a medical technology company focused on transforming the management of hypertension, the leading cardiovascular risk factor in the world. ReCor has pioneered the minimally invasive use of ultrasound in renal denervation, and developed the Paradise™ System, to treat patients with hypertension. The Paradise™ System is an investigational device in the United States. It bears the CE mark in the EU. The company has completed two randomized, sham-controlled studies of the Paradise™ System in patients with both moderate hypertension and those resistant to standard medical therapies. ReCor is currently conducting its FDA IDE pivotal study, RADIANCE-II, in the United States and Europe, and pending successful completion will submit a PMA to the US FDA for market approval.

ReCor Medical is a wholly owned subsidiary of Otsuka Medical Devices Co., Ltd.

<http://www.recormedical.com/>

About Otsuka Medical Devices Co., Ltd.

Otsuka Medical Devices focuses on the global development and commercialization of endovascular therapies that provide new therapeutic options in areas where patient needs cannot be met through pharmaceutical treatment. Otsuka Medical Devices Co., Ltd. is a subsidiary of Otsuka Holdings Co., Ltd., which is listed on the Tokyo Stock Exchange (JP 4578).

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