

## NEWS RELEASE

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

November 7, 2022

**Announced Consistent Reduction of Blood Pressure  
in Pooled Analysis of Three Clinical Trials at AHA 2022***Compiled Data from RADIANCE Global Program Show Consistent Treatment Effect and Safety  
Across Broad Patient Population*

Otsuka Medical Devices Co., Ltd. and ReCor Medical, Inc. (subsidiary of Otsuka Medical Devices) announced consistent and significant blood pressure (“BP”) lowering results across a range of patients with uncontrolled hypertension, including across differences in age, sex, baseline blood pressure, medication level and ethnicity. The results come from analysis of the pooled data from RADIANCE Global Clinical Trial Program: three prospectively powered, randomized and sham-controlled clinical trials which evaluated the endovascular Paradise™ Ultrasound Renal Denervation (uRDN) System in patients with uncontrolled hypertension. The results were presented at the 2022 American Heart Association annual meeting by Dr. Ajay Kirtane, Professor of Medicine at Columbia University, Vagelos College of Physicians and Surgeons and an interventional cardiologist at NewYork-Presbyterian/Columbia University Irving Medical Center.

The RADIANCE Pooled Analysis includes data from more than 500 patients randomized in the three studies from RADIANCE Global Program: RADIANCE-HTN TRIO, which studied patients with resistant hypertension, and RADIANCE-HTN SOLO and RADIANCE II, which studied patients with mild-moderate hypertension. The combined dataset showed an overall reduction in daytime ambulatory systolic BP in the uRDN group of -8.5 mmHg ( $p<0.0001$ ) with a difference between treatment and sham at two months of -5.9 mmHg ( $p<0.0001$ ), favoring uRDN. Blood pressure results were similarly positive in the 24-hour, nighttime, home, and office measures. A favorable safety profile was consistently observed following uRDN treatment across the studies.

“Pooling the data from the RADIANCE program demonstrates that treatment with the Paradise uRDN System results in a consistent reduction in blood pressure across differing severities of hypertension. The consistent and clinically meaningful BP reduction across multiple patient groups increases our interest in the use of uRDN as a potential therapeutic option, when added to lifestyle modification and medications for our patients with uncontrolled blood pressure,” said study co-principal investigator Ajay Kirtane.

“It is very important that the RADIANCE pooled analysis demonstrated a consistent blood pressure reduction in patients across a range of hypertension and both with and without antihypertensive medication, thus broadening the potential applicability of uRDN. Just as important, more than 50% of patients treated with uRDN in the pooled analysis either achieved

daytime ambulatory BP control or had a greater than 10mmHg decrease in daytime ambulatory systolic BP at 2 months, showing the potential benefits of uRDN as an element of a treatment regimen for patients with uncontrolled hypertension,” said study principal investigator Michel Azizi, Professor of Medicine at Université Paris Cité, Hôpital Européen Georges Pompidou, Paris, France.

The RADIANCE Global Program is an international, multicenter, first-of-its-kind initiative designed to explore the benefits of ultrasound renal denervation in hypertension. The RADIANCE studies are double-blind, randomized, sham-controlled trials designed to provide information about the ability of the Paradise uRDN System to treat high blood pressure. All three studies in the RADIANCE Global Program were individually powered for efficacy with a primary endpoint of daytime systolic ambulatory blood pressure at 2 months, and all three met their primary efficacy endpoint with statistical significance at 2 months.

If maintained in the long-term, the blood pressure reductions demonstrated in the RADIANCE pooled analysis correlate to a potential 25% reduction in cardiovascular risk as shown in a meta-analysis of the cardiovascular benefits 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 and Japan.

### **About Otsuka Medical Devices Co., Ltd.**

Otsuka Medical Devices Co., Ltd. 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 is a subsidiary of Otsuka Holdings Co., Ltd. ([www.otsuka.com/en](http://www.otsuka.com/en)), a global healthcare company listed on the Tokyo Stock Exchange (JP 4578).

### **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 Japan, 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.

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