November 30, 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 Submission of Application for Pre-Market Approval of the Paradise™ Ultrasound Renal Denervation (uRDN) System to the U.S. Food and Drug Administration

Filing of Pre-Market Application Follows Successful Pivotal Trial of the Paradise™ uRDN System in the Treatment of Uncontrolled Hypertension

Otsuka Medical Devices Co., Ltd. (“Otsuka Medical Devices”) and ReCor Medical, Inc. (“ReCor”, subsidiary of Otsuka Medical Devices) announced the filing of the pre-market approval (PMA) application to the U.S. Food and Drug Administration (FDA) for the Paradise™ uRDN System in the treatment of uncontrolled hypertension.

The Paradise uRDN System is designed to reduce sympathetic nerve activity by denervating nerves which surround the renal arteries with the goal of reducing blood pressure. Paradise uRDN uses a combination of ultrasound energy to denervate the renal nerves and a water-filled balloon to protect the renal artery. The Paradise uRDN System employs an interventional procedure in which the Paradise catheter is placed in each of the main renal arteries, following which two to three seven-second ultrasound emissions are delivered to denervate the surrounding renal nerves, thereby reducing blood pressure.

Since 2009, ReCor has been focused on developing and testing the Paradise uRDN System to treat hypertension safely and effectively. ReCor has three global, independently powered, sham-controlled randomized clinical trials of the Paradise uRDN System in more than 500 patients with uncontrolled hypertension: RADIANCE-HTN SOLO, RADIANCE-HTN TRIO and RADIANCE II. Each RADIANCE trial met its prespecified primary efficacy endpoint of blood pressure reduction, with positive safety.

RADIANCE II is the U.S. FDA IDE pivotal trial. In September of this year, ReCor and Otsuka Medical Devices announced that the trial successfully reached its primary efficacy endpoint. Results showed a reduction in daytime systolic ambulatory blood pressure of -7.9 mmHg in those treated with uRDN and a difference between uRDN and sham of -6.3 mmHg ($p < 0.0001$). The results from the all three RADIANCE clinical trials have been included in the submission for approval to the U.S. FDA.

Hypertension is the leading contributor to disease burden worldwide, resulting in increased cardiovascular morbidity and mortality, poorer quality of life, and higher costs to health systems.

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), 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. In addition, ReCor has initiated the Global Paradise System (“GPS”) Registry in the EU with plans to expand globally.