Otsuka Holdings Co., Ltd. (“Otsuka Holdings”), Otsuka Medical Devices Co., Ltd. (“Otsuka Medical Devices”) and ReCor Medical, Inc. (“ReCor”) announce the signing of a merger agreement pursuant to which Otsuka Holdings will acquire the remaining shares in ReCor from its current holders. The transaction is subject to approval by ReCor’s shareholders.

Otsuka Holdings’ acquisition follows the announcement by ReCor on June 15 that the U.S. FDA has given its approval to initiate a pivotal clinical study, RADIANCE II, for the evaluation of the Paradise® Renal Denervation System (“Paradise System”) for safe and effective reduction of blood pressure in patients with hypertension. Previously, on May 23rd, ReCor announced at EuroPCR 2018, with simultaneous publication in The Lancet, that its RADIANCE-HTN SOLO (“SOLO”) study of the Paradise System met its primary efficacy endpoint and demonstrated a statistically significant reduction in blood pressure in hypertensive patients.

Following the acquisition, ReCor plans to continue to develop and evaluate the Paradise System in patients with hypertension in preparation for worldwide commercialization, as well as explore its use in additional clinical applications such as heart failure, kidney disease and metabolic disorders, while also building the Otsuka Medical Devices’ incubation and clinical development hub in the U.S. and Europe.

Tatsuo Higuchi, President and Representative Director of Otsuka Holdings, said: “Our decision today reflects not only ReCor’s excellent clinical results, but also the close relationship we have built over the years. Our acquisition of ReCor represents an important step forward for Otsuka’s medical device business, leveraging an innovative technology with Otsuka’s expertise in pharmaceuticals and clinical development.” Kazumichi Kobayashi, Global Renal Denervation Project leader and board member of Otsuka Medical Devices, added: “ReCor’s statistically significant clinical results in the SOLO trial are convincing biological proof that renal denervation with ReCor’s ultrasound-based system is effective in reducing blood pressure in patients with hypertension. We are excited to commercialize this technology, which has the potential to become one of the great technological advancements in hypertension treatment together with the ReCor team.”

Andrew Weiss, President & CEO of ReCor, said: “We are very encouraged by the results of our clinical trials with the Paradise System, which have been conducted in the US and Europe – none of which would have been possible without Otsuka and the strong relationship between our teams. This transaction demonstrates that tremendous value can be created for companies and venture investors through strategic partnerships.” Mano Iyer, COO and Founder, added “We are grateful for the support ReCor has enjoyed from our co-founders Antoine Papiernik of SOFINNOVA Partners and Dr. Jacques Seguin, and our clinical study partners worldwide. We are excited to move forward in our collaboration
with Otsuka to make the Paradise Renal Denervation System a standard of care for treatment of hypertensive patients worldwide.”

About ReCor Medical, Inc.
ReCor Medical is a medical device company that designs and manufactures the Paradise System, a proprietary ultrasound ablation system for renal denervation (RDN). RDN is a new potential therapeutic approach for the treatment of hypertension, one of the most prevalent medical conditions. The Paradise System is approved for sale in the EU and bears a CE mark, but is not approved for sale in the United States. The System's intravascular catheters denervate renal nerves by combining the protection of water-based cooling of the renal artery with high intensity ultrasound energy for circumferential renal nerve ablation. The Paradise System has been studied in clinical trials of approximately 300 patients to date. Following the positive outcomes of the RADIANCE-HTN SOLO trial, ReCor will continue its evaluations of Paradise in RADIANCE-HTN TRIO (a feasibility study of patients with resistant hypertension) and REQUIRE (a pivotal study of patients with resistant hypertension in Japan and Korea), and launch the RADIANCE II pivotal study (a study of patients with moderate hypertension) in the United States and Europe.
http://www.recormedical.com/

About Otsuka Holdings Co., Ltd. and Otsuka Medical Devices Co., Ltd.
Otsuka Holdings Co., Ltd. is the holding company of the Otsuka group, a global healthcare group headquartered in Tokyo, Japan. With operations in pharmaceuticals, nutraceuticals, medical devices and other health-related businesses, the group generated worldwide sales of JPY1,240 billion in the fiscal year ended December 2017.
http://www.otsuka.com/en/

Established in 2011, Otsuka Medical Devices Co., Ltd. is a fully-owned subsidiary of Otsuka Holdings and one of its core operating subsidiaries. Otsuka Medical Devices focuses on the development and commercialization of endovascular devices that provide new therapeutic options in areas where patient needs cannot be met through pharmaceutical or other conventional treatment. Otsuka Medical Devices conducts the REQUIRE trial for renal denervation in hypertensive patients (n=140), who are uncontrolled on 3 or more medications including a diuretic, in Japan and Korea through its subsidiary JIMRO Co., Ltd.