

December 10, 2020

Otsuka Announces Results of Two International Clinical Studies in Patients with Treatment Resistant Hypertension and Breakthrough Device Designation for Paradise™ Ultrasound Renal Denervation System for Uncontrolled Hypertension

Otsuka Medical Devices Co., Ltd. (“Otsuka Medical Devices”), a fully owned subsidiary of Otsuka Holdings Co., Ltd., today announces the results of the RADIANCE-HTN TRIO (“TRIO”) trial (NCT02649426), conducted in the US and Europe, and of its REQUIRE study (NCT02918305), conducted in Japan and South Korea, as well as the granting of Breakthrough Device Designation by the US FDA for Paradise™ Ultrasound Renal Denervation System (the “Paradise™ System”) for patients with uncontrolled hypertension, who may be inadequately responsive to, or who are intolerant to anti-hypertensive medications. Both TRIO and REQUIRE were prospective, multi-center, randomized, blinded, sham-controlled trials with the objective of evaluating the Paradise™ System in patients with treatment resistant hypertension.

The TRIO trial evaluated the efficacy and safety of the Paradise™ System in uncontrolled, treatment-resistant hypertensive patients (n=136) wherein all subjects were placed on a single-pill combination-drug containing 3 hypertension medications (a calcium-channel blocker, an angiotensin II-receptor blocker, and a diuretic) and after confirmation of treatment-resistant hypertension, were then randomized 1:1 with a Paradise™ System treatment compared to a sham procedure control group (“Sham”). A total of 53 study centers were involved in the trial in 7 countries. TRIO results met the primary efficacy endpoint, thus showing a significant difference in the reduction in daytime blood pressure (Daytime ABPM) between baseline and 2-month follow-up in the treatment arm compared to Sham. No major safety issues were observed.

RADIANCE-HTN TRIO is the second FDA IDE, randomized, sham-controlled study of the Paradise™ System in patients with hypertension (following the RADIANCE-HTN SOLO study) conducted by ReCor Medical (a wholly-owned subsidiary of Otsuka Medical) to meet its primary efficacy endpoint and demonstrate a positive treatment effect. In addition, ReCor Medical is conducting an FDA IDE pivotal study, RADIANCE-II, in patients with mild-to-moderate hypertension (n=225), with the goal to submit for PMA approval.

Separately, the FDA granted the ReCor Paradise™ System the Breakthrough Device Designation. Under the Breakthrough program, the FDA provides priority review and interactive communication during the premarket review process, with the goal to accelerate regulatory path and commercialization in the United States.

The REQUIRE trial evaluated the efficacy and safety of the Paradise™ System in patients with uncontrolled, treatment-resistant hypertension (n=143) on 3 or more hypertension medications measured by the difference between baseline 24-hour ambulatory blood pressure (24-hour ABPM) and 24-hours ABPM at 3-months following randomization in the treatment arm compared to sham. Whereas no major safety issues were observed, REQUIRE failed to meet its primary efficacy endpoint.

Additional information regarding both TRIO and REQUIRE will be announced in due course.

About Ultrasound Renal Denervation Therapy for the Treatment of Hypertension

Hypertension is one of the world's most prevalent medical conditions. Despite many years of effort and the availability of numerous medications for its treatment, millions of patients worldwide remain with uncontrolled hypertension, often resistant to medical therapy. Renal denervation with the Paradise™ System is a new potential treatment of hypertension based on reducing renal sympathetic nerve overactivity, in patients for whom conventional hypertension therapy has proven unsuccessful, through denervation of the renal nerves. The Paradise™ System's intravascular catheters denervate renal nerves by short, controlled, circumferential emissions of high intensity ultrasound energy for renal nerve ablation while protecting the renal artery with cooling from a water-filled balloon. The Paradise™ System has been studied in clinical trials of more than 400 patients to date.

About the FDA Breakthrough Devices Program

The FDA Breakthrough Devices Program is intended to help patients receive more timely access to breakthrough medical technologies that have the potential to provide more effective treatment for life-threatening or irreversibly debilitating diseases or conditions.

About Otsuka Medical Devices

Otsuka Medical Devices focuses on the global 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 Co., Ltd. is a subsidiary of Otsuka Holdings Co., Ltd. (www.otsuka.com/en), a leading global healthcare group listed on the Tokyo Stock Exchange (JP 4578). <https://www.umd.otsuka.com/en/>

About ReCor Medical

ReCor Medical, headquartered in Palo Alto, CA, is a wholly owned subsidiary of Otsuka Medical Devices Co., Ltd. focused on transforming the management of hypertension, one of the leading cardiovascular risk factors. 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 is approved for sale in the EU and bears a CE mark. The company has completed two IDE randomized, controlled studies of the Paradise™ System in patients with moderate hypertension and those resistant to standard medical therapies. ReCor is currently conducting its FDA IDE pivotal study, RADIANCE-II, and pending successful completion will submit for PMA approval.

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