

Dealdoc

Development and marketing agreement for Paradise ultrasound-based renal denervation system

ReCor Medical Otsuka

May 16 2016

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Companies: ReCor Medical
Otsuka
Announcement date: May 16 2016
Deal value, US\$m: n/d

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Details

Announcement date: May 16 2016

Bigpharma

Industry sectors: Medical device

Pharmaceutical

Exclusivity: Exclusive

Therapy areas: Cardiovascular » Hypertension

Genitourinary

Technology types: Diagnostics » Imaging » Ultrasound

Deal components:

Development

Marketing

Asia

Asia » China

Geographic focus:

Asia » Japan

Asia » North Korea

Europe

North America » United States

Financials

Deal value, US\$m: n/d

Termsheet

ReCor Medical announced the signing of a development and commercialization agreement, together with an additional investment, with Otsuka Holdings, a global healthcare group headquartered in Tokyo, Japan.

As part of the agreement, Otsuka Holdings obtained exclusive rights to commercialization of the ReCor Paradise ultrasound-based renal denervation system for Japan, China, Korea and other Asian countries.

Otsuka Holding's investment will be used to further ReCor's clinical studies in the US and Europe.

Under the commercialization agreement, Otsuka will have exclusive rights to conduct clinical trials, regulatory activities and sales and marketing functions for commercialization of the ReCor Paradise technology for renal denervation in Asia.

Otsuka's initial focus will be to conduct a clinical trial of the Paradise System in Japan to demonstrate its potential benefit in patients with treatment-resistant hypertension.

ReCor plans to use the Otsuka funding to advance its IDE-approved RADIANCE-HTN study for evaluation of the Paradise System in patients with hypertension in the US and EU.

The study recently began enrolling at sites in the United States, The Netherlands, and the UK, and additional sites are planned for France and Germany.

Press Release

PALO ALTO, Calif. and AMSTERDAM, May 16, 2016 /PRNewswire/ -- ReCor Medical ("ReCor") announced today the signing of a development and commercialization agreement, together with an additional investment, with Otsuka Holdings ("Otsuka Holdings"), a global healthcare group headquartered in Tokyo, Japan. As part of the agreement, Otsuka Holdings obtained exclusive rights to commercialization of the ReCor Paradise® ultrasound-based renal denervation system for Japan, China, Korea and other Asian countries. Otsuka Holding's investment will be used to further ReCor's clinical studies in the US and Europe.

Under the commercialization agreement, Otsuka will have exclusive rights to conduct clinical trials, regulatory activities and sales and marketing functions for commercialization of the ReCor Paradise technology for renal denervation in Asia. Otsuka's initial focus will be to conduct a clinical trial of the Paradise System in Japan to demonstrate its potential benefit in patients with treatment-resistant hypertension.

ReCor plans to use the Otsuka funding to advance its IDE-approved RADIANCE-HTN study for evaluation of the Paradise System in patients with hypertension in the US and EU. The study recently began enrolling at sites in the United States, The Netherlands, and the UK, and additional sites are planned for France and Germany.

Tatsuo Higuchi, President and Representative Director of Otsuka Holdings, said, "We are excited to commercialize ReCor's unique ultrasound-based renal denervation technology in Asia. This collaboration demonstrates Otsuka's strategy of leveraging our expertise in select disease areas for the development of medical device-based solutions with the potential to address medical needs that cannot be met by pharmaceutical treatment alone."

Andrew M. Weiss, President & CEO of ReCor, commented: "We highly value Otsuka's development and marketing capabilities in Asia one of the most important potential markets for our Paradise technology. Otsuka has been one of our most important investors since leading our Series D financing, joining Sofinnova Partners and RICA Universal in funding ReCor. This latest investment is designed to fund our RADIANCE-HTN study, which we hope will demonstrate the blood-pressure lowering effect of the Paradise System in patients with hypertension."

About ReCor Medical, Inc.

ReCor Medical is a private medical device company that designs and manufactures a proprietary ultrasound ablation system for renal denervation (RDN) called the Paradise System®. 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. ReCor has initiated enrollment in its RADIANCE-HTN study, en IDE-approved, randomized, sham-controlled trial to demonstrate the efficacy of the Paradise System in patients with hypertension. RADIANCE-HTN is being conducted in approximately 35 centers in the United States, Netherlands, UK, France and Germany.

More information on RADIANCE-HTN can be found at:

https://clinicaltrials.gov/ct2/show/NCT02649426?term=radiance&rank=3

For more information about ReCor Medical, please visit www.recormedical.com or contact Andrew M. Weiss, President & CEO, ReCor Medical at aweiss@recormedical.com / +1-650-542-7700.

About Otsuka Holdings Co., Ltd.

Not available.

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 approximately JPY1,445 billion in the fiscal year ended December 2015. Under its corporate philosophy, "Otsuka people creating new product for better health worldwide", the Otsuka Group conducts research, development, manufacturing and marketing of innovative products that are uniquely positioned to provide advanced therapy, improve quality of life and support a healthy lifestyle.
Filing Data
Tilling Data
Not available.