

Metavention's Renal Denervation Pivotal IDE Study now Approved by FDA for the Treatment of Hypertension

MINNEAPOLIS, June 21, 2023/PRNewswire/ -- Metavention, Inc. has received US Food & Drug Administration (FDA) approval to initiate its RADAR Pivotal IDE study to determine the safety and efficacy of their Integrated Radio Frequency (iRF) Renal Denervation System, for the treatment of hypertension. RADAR Pivotal is a randomized, double-blinded, sham-controlled study, that will allow up to 300 patients to be enrolled at 50 participating centers.

Overactive sympathetic nerves in the kidneys can contribute to high blood pressure. Renal denervation of the kidneys (RDN) is a minimally invasive procedure which inhibits sympathetic nerve overactivity. Metavention's iRF Denervation System provides an important distinction to RDN procedures in that it requires only a single ablation cycle per kidney. With the emergence of RDN as a potential treatment option in the care continuum of hypertension, the iRF Denervation System intends to simplify these procedures and reduce the overall burden on patients undergoing RDN.

Todd Berg, CEO of Metavention commented, "The benefits of renal denervation for the treatment of uncontrolled hypertension has been meticulously studied for over a decade, the procedure could represent a new frontier in hypertension management for interventionalists. This pivotal study of the iRF Denervation System is a tremendous opportunity to bring next-generation capabilities to this emerging field."

About Metavention, Inc.

Metavention, Inc. is a privately held medical device company headquartered in Minneapolis Minnesota, and the developer of the iRF Denervation System, a catheter-based, minimally invasive renal denervation procedure, intended for the treatment of hypertension.

The iRF Denervation System uses an integrated multi-RF electrode balloon with a cooling circuit to provide renal denervation in a single ablation cycle. By requiring only one ablation per kidney, the iRF System is intended to significantly simplify and standardize the denervation procedure.

The iRF Denervation System is an investigational device, limited to use in studies only, and is not currently approved in any geography.

About Hypertension (High Blood Pressure)

High blood pressure is a common condition in which the force of blood pressure against the artery walls is great enough that it may eventually cause serious health problems. Potential complications of uncontrolled hypertension include heart attack, stroke, aneurysm, and heart failure. Hypertension is the leading preventable cause of premature death worldwide. Hypertension has historically been treated with lifestyle modifications and medication but the prevalence of patients suffering from uncontrolled hypertension continues to increase.

For more information, please visit www.metavention.com.