Man & Science announces U.S. FDA Breakthrough Device Designation Granted for the treatment of Chronic Cluster Headache

BRUSSELS, MONT-SAINT-GUIBERT, BELGIUM, November 8, 2021 /EINPresswire.com/ -- Man & Science SA, a private medical device company focused on the development of innovative solutions for headache disorders, announced today that it has been granted a Breakthrough Device Designation by the Center of Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) for its minimally invasive innovative neuromodulation therapy for the treatment of Chronic Cluster Headache (CCH).

The FDA's Breakthrough Designation Program aims to help patients and healthcare providers to receive timely access to breakthrough technologies with potentially more effective treatment of life-threatening or irreversibly debilitating diseases or conditions.

Under the Program, the FDA will provide the Man & Science's OCCIPITAL NERVE FIELD STIMULATION SYSTEM (ONFS) with priority review and interaction with FDA's experts throughout the premarket review phase.

"We are pleased to have received Breakthrough Device Designation for our proprietary ONFS system for CCH patients, recognizing that our solution is innovative. This Breakthrough Designation should accelerate our market authorization process in the US." said Robert Taub, CEO of Man & Science.

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