December 27, 2022
Sawai Pharmaceutical Co., Ltd.

Sawai Pharmaceutical Applies for Marketing and Manufacturing Approval for Non-Invasive Neuromodulation Device

Osaka, Japan – December 26, 2022 – Sawai Pharmaceutical Co., Ltd. (Head office: Osaka, Japan, President: Kenzo Sawai) submitted an application to the Pharmaceuticals and Medical Devices Agency (PMDA) for marketing and manufacturing approval for the non-invasive neuromodulation device, SWD001, as a medical device for acute treatment of migraine.

SWD001 is a non-invasive neurostimulation system designed to concurrently stimulate the occipital and trigeminal nerve branches to modulate brain regions associated with migraine. In January 2021, Sawai Pharmaceutical and Neurolief entered into an exclusive development and marketing agreement to make SWD001 available in Japan. Neurolief has received both Food and Drug Administration (FDA) clearance in the US as well as CE mark approval in Europe for the acute treatment of migraine. This application to the PMDA is based on the results of clinical trials conducted overseas to evaluate effectiveness and safety of migraine treatments using SWD001.

According to a national survey, the prevalence of migraine in Japan is 8.4% overall which means approximately ten million people suffer from this disease. Acute migraine is predominantly treated with medication, however, insufficient treatment results and a drop in patient adherence due to adverse events have been identified. The data also demonstrates that 70% of migraine patients have not visited a medical institution. SWD001 is expected to increase patient satisfaction and QoL through appropriate treatment at medical institutions.

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