

PRESS RELEASE

November 3, 2020

Salvia BioElectronics, High Tech Campus 41, Eindhoven, The Netherlands

Salvia BioElectronics receives FDA Breakthrough Device Designation for innovative neurostimulation solution

Bioelectronics solution addresses drug-refractory chronic migraine

Eindhoven, the Netherlands, November 3, 2020 – Salvia BioElectronics B.V. (“Salvia”), a neurostimulation platform company targeting chronic migraine, announced today that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Device Designation for its implantable neurostimulation system to address chronic migraine.

Salvia is developing an innovative neurostimulation solution for chronic migraine based on a novel device concept with unique benefits to both patients and physicians. Migraine is the first cause of disability in under 50s, affecting one out of seven people, predominantly women¹. People with migraine experience episodes of throbbing, pulsating pain, sometimes accompanied by nausea, vomiting, and sensitivity to light, that can last anywhere from a few hours to a few days. More than five percent of patients suffer from chronic migraine, where they experience migraines for an average of 22 days per month². Migraine does not only impact wellbeing; it has an enormous impact on work, school, family and social lives.

Wim Pollet, Chief Medical Officer of Salvia BioElectronics, noted: *“The FDA breakthrough device designation of our neurostimulation system reflects the recognition of the large unmet medical need of patients suffering from refractory chronic migraine, and the potential of Salvia’s bioelectronic foil technology to address this. We look forward to working closely with the FDA to expedite the review process, to accelerate the development of our therapy.”*

Patients with chronic migraine suffer from 15 or more headache days per month, with an average of 22 days per month, despite best medical treatment¹. Only 1 in 3 of drug-refractory chronic patients are helped with the newest generation of anti-migraine drugs, leaving many patients in medical need.

While neurostimulation has been demonstrated to be effective for these patients, there are no approved devices commercially available. Salvia was founded with the mission to help these patients suffering from chronic migraine by developing thin and conforming bioelectronic foils that uniquely adapt to the anatomy of the head.

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¹ Steiner, T.J., Stovner, L.J., Vos, T. et al. Migraine is first cause of disability in under 50s: will health politicians now take notice?. *J Headache Pain* 19, 17 (2018). <https://doi.org/10.1186/s10194-018-0846-2>

² Richard B Lipton, Merle L Diamond, Stewart J Tepper, *Expert Perspectives—Migraine Prevention for Highly Impacted Patients*.

[The FDA's Breakthrough Devices Program](#) has been established to help patients to have more timely access to medical devices that provide more effective treatment for irreversibly debilitating diseases or conditions. The designation allows Salvia BioElectronics to have more frequent interaction with the FDA regulatory experts when preparing its FDA submissions, followed by prioritized reviews.

ENQUIRIES

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NOTES TO EDITOR

ABOUT SALVIA BIOELECTRONICS B.V. (SALVIA BIOELECTRONICS)

Salvia BioElectronics is an innovative Dutch startup active in the emerging field of bioelectronics. Salvia BioElectronics was founded in 2017 by neuromodulation industry veterans with the ambition to develop a bioelectronics therapy for people suffering from chronic migraine that is as easy as taking medication yet side-effect free. Building on research around known neural targets in migraine, the startup is working to develop the right form factor for stimulation that is effective, safe, and affordable.

Migraine is the first cause of disability in under 50s, affecting one out of seven people, predominantly women. People with migraine experience episodes of throbbing, pulsating pain, sometimes accompanied by nausea, vomiting, and sensitivity to light, that can last anywhere from a few hours to a few days. More than five percent of patients experience migraines for 15+ days per month – with an average of 22 days – a condition described as chronic migraine.

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