

### **PRESS RELEASE**

### FOR IMMEDIATE RELEASE

# Sapiens reports positive preliminary results from intra-operative deep brain stimulation study

First proof for steering brain stimulation in patients using Sapiens' SureStim-1 lead

Munich, Germany, and Eindhoven, the Netherlands, May 29, 2013 - Sapiens Steering Brain Stimulation B.V. (Sapiens), an emerging medical device company developing brain stimulation products, today announced positive preliminary results from the intra-operative "FAME" clinical study of its SureStim-1 deep brain stimulation lead. The preliminary data were presented today by neurosurgeon Dr. P.R. Schuurman at the 16<sup>th</sup> international meeting of the World Society for Stereotactic and Functional Neurosurgery in Tokyo.

Deep brain stimulation (DBS) is approved worldwide for the treatment of Parkinson's disease (PD), essential tremor, dystonia, obsessive-compulsive disorder (OCD) and more recently for the treatment of epilepsy. It is a therapy that relies on the delivery of mild electrical pulses to specific areas in the brain via an implanted lead that is connected to a battery-powered implantable pulse generator. Several clinical groups are currently investigating the application of DBS for other neurological and psychiatric disorders.

Sapiens is developing an innovative high-resolution DBS implant with the capacity to steer electrical pulses away from areas of the brain that can produce undesirable side-effects. The SureStim-1 system will provide the clinician with more flexibility in adjusting and fine-tuning, which is expected to result in uncompromised therapeutic benefits for patients. In addition, supporting products are being developed to allow for faster implantation procedures and more effective programming of the system in patients. Together, these innovations allow more patients to benefit from DBS while minimizing side-effects, and reducing time and resources for the complex procedure.

The intra-operative FAME (First-Acute-Man-Evaluation) study is the first clinical investigation into the safety and efficacy of stimulation with Sapiens' new high-resolution SureStim-1 lead. During a conventional DBS implantation surgery, the Sapiens' lead was temporarily inserted for stimulation and recording tests in 8 Parkinson's disease patients. This pilot study was recently concluded at the Department of Neurosurgery, Academic Medical Center (AMC), Amsterdam, The Netherlands.

In his presentation at the aforementioned conference, Dr. Schuurman, lead investigator of the study and a member of Sapiens' Medical Advisory Board, summarized the data, noting that within the limitations of an intra-operative setting, the initial observations demonstrated the ability of Sapiens' lead to steer stimulation. In addition, he explained the interesting option to simultaneously record multiple brain signals that was demonstrated in the trial.

Hubert Martens, Co-Founder and Director of Clinical Science at Sapiens commented: "We are very pleased with these preliminary results from the first clinical investigation with our novel Steering DBS lead. This is a major milestone for our company and moves us another step closer to market introduction."



# **About Sapiens Steering Brain Stimulation**

Sapiens Steering Brain Stimulation is an emerging medical device company with a mission to bring the innovative concept of Steering Deep Brain Stimulation (DBS) to more patients who can benefit from this advanced treatment of degenerative or functional brain disorders, such as Parkinson's disease, dystonia and other currently emerging indications.

Sapiens' ambition is to improve the therapeutic efficacy of DBS, to shorten and simplify the clinical procedure, and to improve patient comfort. Sapiens' high-resolution probe enables the reduction of stimulation-induced side-effects by precisely shaping the stimulation field to the intended target area. The SureSuite® products, SurePlan®, SurePlace® and SureTune®, provide an integrated, image-based solution for planning and programming an optimal DBS treatment. SureStim-1®, the Sapiens implant, is MRI-conditionally safe, and controls the steering.

With offices in Eindhoven, the Netherlands and Munich, Germany, Sapiens was founded in 2011. The company is a spin-out of Royal Philips, and is backed by Wellington Partners, Edmond de Rothschild Investment Partners, Life Sciences Partners (LSP), the Wellcome Trust and INKEF Capital. Additional support is provided by the Michael J Fox Foundation and the European Union Framework Program VII. Sapiens' Steering Brain Stimulation probe, implant and image-guided programming are all based on patented technologies.

For more information please visit www.sapiensneuro.com.

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