

WISE enrolls first patient in pivotal clinical study of novel neuro-electrodes for brain monitoring

*Milestone reached in development of highly ergonomic and minimally invasive
cortical strip electrodes*

Milan, Italy, 7 May 2019 - WISE Srl, a medical device company developing next-generation implantable leads for neuromonitoring and neuromodulation, has enrolled its first patient in the pivotal clinical study of its WISE Cortical Strip.

The WISE Cortical Strip is a single use medical device for IntraOperative Neurophysiological Monitoring during brain tumour and epilepsy surgeries. It is used for continuous recording of the brain's electrical activity and for brain stimulation.

The [WIN Study](#) (WISE Cortical Strip for Intraoperative Neurophysiological Monitoring study) is a prospective, interventional, multi-center, open-label premarket study, expected to enroll approximately 33 patients. Designed to confirm the safety and performance of the WISE Cortical Strip, the first patient has been enrolled at Universitätsspital Zürich. The study is being carried out at four clinical centres in Germany and Switzerland: Munich University Hospital, Inselspital Bern and Kantonsspital Luzern in addition to the Zurich centre.

The WISE Cortical Strip is unique as it is made of pliable platinum electrodes embedded in a soft, thin film of silicone, overcoming the stiffness and rigidity of traditional cortical strips. It is highly ergonomic and conformable even on surfaces as soft and wrinkly as the brain. WISE's proprietary and patented metallization technology enables stretchable and pliable electronic microcircuits to be inserted into biocompatible silicones. This allows much better adhesion to the brain surface, minimal invasion, excellent adaptability and low impedance of the electrical circuit.

The study is due to conclude in Q3 2019, with the results to be published shortly afterwards.

CEO of WISE, Dr. Luca Ravagnan said: *"Initiating the pivotal study of our WISE Cortical Strip is a key milestone for us as we work towards CE approval and commercialization. Patient enrollment is on schedule and we look forward to feedback from the surgeons on ease of use and low electrical impedance."*

PD Dr. med. Neidert from Universitätsspital Zürich said: *"We have been impressed so far with the ability of the WISE Cortical Strip to tightly adhere to the brain surface without the need of any pressure, allowing to obtain low impedance contact from all the electrodes of the strip. The electrodes are also easy to position, which is not something you would expect in a very flexible electrode"*.

Prof. Dr. med. A. Szelényi from Munich University Hospital, Coordinating investigator of the WIN Study concluded: *"The WISE Cortical Strip is an exciting technology and we look forward to seeing the final study results."*

****ENDS****

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About WISE Srl

WISE is developing a genuinely new generation of Neuromonitoring and Neuromodulation electrodes by means of its proprietary Supersonic Cluster Beam Implantation (SCBI) technology.

Neuromonitoring and Neuromodulation require electrodes and leads to be surgically implanted on neural tissues (as for instance the brain and the spinal cord) to apply electrical stimuli or to record the electrical activity. The leads produced using WISE's new SCBI technology consist of stretchable electronic circuits integrated in very thin elastomeric foils. As a result, WISE's electrodes are highly ergonomic, conformable, soft and thin, thus allowing great adhesion, minimal invasiveness and excellent adaptability on neural tissues.

In parallel with the clinical trial for its first product for Neuromonitoring, the WISE Cortical Strip (WCS), WISE is developing the first EXpandable PERcuTaneous SCS lead (SCS EXPERT™ lead) for the treatment of chronic pain by Neuromodulation, a market with large constant growth rates and an unmet medical need.

Founded in 2011 by a team of material scientists coming from the University of Milan, WISE has so far received funding from Agite!, Atlante Seed and Atlante Ventures, b-to-v, HTGF, Principia SGR and private investors. Since 2016 the Company has established its Production Plant in Cologno Monzese, Milan, Italy (1000 m² wide, comprising cleanrooms and production laboratories compliant for the manufacturing of implantable medical devices) and has an office in Berlin, Germany.

For more information, please visit: www.wiseneuro.com.

About Universitätsspital Zürich

Universitätsspital Zürich is regarded as one of the top neurosurgical teaching and research hospitals in Switzerland and in Europe. The founding of neurosurgery allowed the Swiss school of neurosurgery to develop and influenced the rise of modern neurosurgery in Europe. Over the decades, it has laid the grounds for important developments in the specialty; in particular, in the areas of vascular, skull base, epilepsy and neuro-oncological surgery. As such, it continues to be among the top teaching institutions not only in Switzerland, but also in Europe, and is visited by many students, postdocs and surgical fellows.



About Munich University Hospital

Munich University Hospital (LMU) treats around 500,000 outpatients, inpatients and semi-residential patients each year at its Großhadern and City Centre Campuses. Just over 2,000 beds are available to its 29 specialist clinics, eleven institutes and five departments, and its 45 interdisciplinary centres. Of a total of 9,450 employees, around 1,600 are doctors and 3,200 are nursing staff. Munich University Hospital has been a public-law institution since 2006. Together with the Medical Faculty of Ludwig Maximilians University, Munich University Hospital is involved in four special research areas of the German Research Foundation (SFB 684, 914, 1054, 1123), three Transregios (TRR 127, 128, 152) belonging to Clinical Research Group 809, and two Graduate Colleges belonging to the German Research Foundation (GK 1091, 1202). This is in addition to the Center for Integrated Protein Sciences (CIPSM), Munich Center of Advanced Photonics (MAP), Nanosystems Initiative Munich (NIM) and Munich Cluster for Systems Neurology (SyNergy) – all institutes of excellence – and the Graduate School of Systemic Neurosciences (GSN-LMU), the Graduate School of Quantitative Biosciences Munich (QBM) and the Graduate School Life Science Munich (LSM).

For more information, please visit: www.klinikum.uni-muenchen.de.
