

## WISE completes enrolment in pivotal clinical study of novel neuro-electrodes for brain monitoring

*Highly ergonomic and minimally invasive  
cortical strip electrodes on track for commercialization in 2020*

**Milan, Italy, 23 January 2020** - WISE Srl, a medical device company developing next-generation implantable leads for neuromonitoring, neuromodulation and brain-machine interfacing, has completed enrolment in the pivotal clinical study of its first product, the WISE Cortical Strip.

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

The [WIN Study](#) is a prospective, interventional, multi-center, open-label premarket study performed in expert centers in Germany, Switzerland and Italy. The study is designed to confirm the safety, performance and intended use of WCS for CE and 510K certification purposes.

The study has enrolled a total of 32 patients at Munich University Hospital, Universitätsspital Zürich, Inselspital Bern and University Hospital of Verona. Early data indicates that the WCS has overcome the stiffness and rigidity of traditional cortical strips, resulting in excellent adaptability and better performance in terms of impedances. WISE's proprietary and patented metallization technology enables stretchable and pliable electronic microcircuits to be embedded into biocompatible silicones.

**Luca Ravagnan, CEO of WISE** said *"This is a crucial milestone on our journey towards commercializing our first product. The high level of investigator engagement was a key factor in completing enrolment and I'm looking forward to making this technology available for patients and physicians. Our full results will be published later this year and will be used to complete CE Mark and 510k certification."*

**Prof. Dr. med. A. Szelényi from Munich University Hospital, coordinating investigator of the WIN Study** concluded: *"I am pleased that patient recruitment was completed and would like to express my thanks to all collaborators in this multi-center study. Now, we are looking forward to the final analysis, discussion and presentation of the results."*

WISE Srl will be exhibiting at the Annual Meeting of The North American Neuromodulation Society (NANS), Las Vegas, 23-26 January 2020, and will be presenting at the Emerging Technology Forum of NANS on the 23rd January 2020 on company's products and technology *"Soft electrodes: New frontiers for brain-machine interfaces"*.

For more information about the meeting please visit:  
<https://conference.neuromodulation.org/>

**\*\*ENDS\*\***

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### **About WISE Srl**

WISE is developing a genuinely new generation of leads for Neuromonitoring, Neuromodulation and Brain Machine Interfacing 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 m<sup>2</sup> 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](http://www.wiseneuro.com)

### **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](http://www.klinikum.uni-muenchen.de)

#### **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.

For more information, please visit: [www.en.usz.ch](http://www.en.usz.ch)

#### **About Inselspital Bern**

The Inselspital, also named the University Hospital of Bern, is one of the five university hospitals of Switzerland. Currently, the hospital employs a staff of over 7,200 and provides care for 250,000 patients each year. It also provides practical training to 600 medical students and over 1,000 other healthcare professionals.

For more information, please visit: [www.inselgruppe.ch/de/](http://www.inselgruppe.ch/de/)

#### **About University Hospital of Verona**

The University Hospital of Verona is the second largest hospital trust in Italy in terms of the number of hospital beds, and the fifth largest in term of admission. All the “high specialties” are to be found in the University Hospital of Verona, from heart surgery to organ transplant, from pediatric oncohaematology to the serious burns unit to IORT (intraoperative radiotherapy). All of them guarantee diagnosis, therapy and care of a very high standard, achieved also through the use of an interdisciplinary approach.

For more information, please visit: [www.ospedaleuniverona.it/ecm/home](http://www.ospedaleuniverona.it/ecm/home)