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Next Important Milestone Reached for First-in-Human Implantation of the CorTec Brain Interchange System as a Therapeutic Brain-Computer Interface

CorTec has announced today that Institutional Review Board from University of Washington (IRB) has approved the Feasibility study for stroke rehabilitation using the Brain Interchange System. This marks a significant milestone and paves the way for the system's clinical investigation in the United States. The IRB approval follows the recent Investigational Device Exemption (IDE) granted by the U.S. Food and Drug Administration (FDA), setting the stage for the study to proceed to participant recruitment.

IRB approval is a critical step in the clinical research process, especially for studies involving human subjects. While FDA approval ensures the safety and technical readiness of the device being studied, the IRB provides an essential layer of oversight to safeguard the ethical conduct of the research. The IRB's review takes into account the specific local context of the research site, including the population being studied and the resources available, to ensure participant safety. This local oversight is crucial, as it tailors the ethical review process to the unique circumstances of each study, beyond the federal standards.

"Securing FDA approval for our IDE study[1] was a thorough process that involved the submission of extensive documentation from both our team at the University of Washington and the device manufacturer, CorTec," said Dr. Jeffrey Herron, Assistant Professor at the University of Washington and co-investigator on the NIH-funded study[2]. "The FDA's evaluation focused on the study protocol, hazard analysis, and the device design to ensure readiness for human implantation. Achieving this IDE approval was a critical milestone, and with the following IRB approval, we are now prepared to move forward with participant recruitment."

According to Dr. Martin Schuettler, CorTec's CTO, the Brain Interchange System's closed-loop functionality is a groundbreaking achievement that opens new avenues for highly individualized treatments. "I am incredibly proud of this milestone," Dr. Schuettler expressed. "Our system enables a seamless exchange of information between biology and technology, which is why we named it the CorTec Brain Interchange. With this system, we are not only providing the critical technological tools needed to advance new therapies but also shaping the future of brain-computer interfaces and paving the way for future therapy discoveries."

CorTec is collaborating with leading experts in the U.S. to further the development of innovative therapies using the Brain Interchange System. The first Investigational Device Exemption (IDE) study will be conducted in collaboration with Professor Jeffrey G. Ojemann from the University of Washington School of Medicine in Seattle and Professor Steven C. Cramer from the University of California, Los Angeles. Funded by the U.S. National Institutes of Health (NIH), this consortium aims to gather initial safety data and develop novel therapeutic rehabilitation approaches for upper limb impairment in stroke patients through direct cortical electrical stimulation delivered by the Brain Interchange System[2].

Patient enrollment and the first implantation of the neural interfacing system are scheduled for the fourth quarter of 2024, marking the beginning of a new chapter in stroke rehabilitation research.

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References:

[1] IDE Application reference G230003/A001
[2] NIH Project 1UH3NS121565-01A1: ” Motor Recovery through Plasticity-Inducing Cortical Stimulation”, in response to RFA-NS-18-023: https://reporter.nih.gov/search/-xvTvG85Ukm-KXyunAWaJw/project-details/10357993

About CorTec

CorTec was founded in 2010 in Freiburg, Germany. CorTec offers high-quality neurotechnology to industry and clinics. CorTec is offering components and active systems that allow users in industry and clinic to explore new clinical applications and to develop Medical Devices for specific indications. The heart of CorTec’s product portfolio is the Brain Interchange System, which is a fully implantable investigational device for both sensing and stimulating on 32 channels. The system is designed for discovery of novel therapies for the central nervous system and for the exploration of brain-computer interface applications.

On basis of the Brain Interchange CorTec also offers the Brain Interchange Evaluation Kit, which is a bench-top-version of the actual implant for testing and validation of your intended therapy. It is electrically identical to the implant and is therefore the ideal entrance to the clinical use of the brain interchange system.

Based on the Brain Interchange Technology, CorTec offers individualized solutions for components of active implants. The Brain Interchange System as well as each component can be individualized to meet indication specific requirements – as a system solution or single component design. CorTec is offering the °AirRay Electrode Technology, high-channel implant housing technology and other components/technologies as service to 3rd parties. CorTec provides its customers with individual systems and components to interface the central and peripheral nervous system.

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