Press Release
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CorTec's Brain Interchange™ Accepted into FDA Total Product Life Cycle Advisory Program (TAP)

Third patient successfully implanted at Harborview Medical Center as NIH-funded stroke trial advances

Freiburg, Germany, April 23, 2026 - CorTec GmbH today announced that the U.S. Food and Drug Administration (FDA) has accepted the company into its Total Product Life Cycle Advisory Program (TAP), recognizing the Brain Interchange™ BCI system as a priority innovation in stroke motor rehabilitation. The TAP enrollment follows the recently granted FDA Breakthrough Device Designation, putting CorTec among a limited number of neurotech companies to receive both recognitions. Additionally, a third patient has been successfully implanted at Harborview Medical Center in Seattle as part of the ongoing NIH-funded, FDA-approved clinical trial conducted by researchers from the University of Washington and UCLA.

The FDA's TAP Program is open to a limited number of breakthrough medical technologies. TAP provides companies with a dedicated FDA liaison, accelerated feedback on study design and regulatory strategy, and early engagement with payers and clinicians, including the Centers for Medicare & Medicaid Services (CMS). For CorTec, TAP acceptance means structured, end-to-end support from early clinical development through to market access and reimbursement. The program is designed to de-risk the path to approval and help establish reimbursement frameworks for entirely new therapy classes.

"TAP acceptance places CorTec at the forefront of a field dominated by U.S. players and confirms that European deep-tech innovation can compete at the highest level of global medtech development," said **Dr. Frank Desiere, CEO of CorTec.** "Beyond the competitive significance, TAP as well as the recently received Breakthrough Device Designation highlight a strong regulatory momentum and mark the beginning of a structured path toward making Brain Interchange™ accessible to stroke patients worldwide. With closer FDA engagement and early interaction with payers, we can now build the clinical evidence and reimbursement framework for this entirely new therapy class."

In parallel with these regulatory milestones, the Brain Interchange™ clinical study continues to advance. A further participant has been successfully implanted at Harborview Medical Center in Seattle, bringing the study cohort to three patients. The growing dataset will enable investigators to assess the system's performance and therapeutic impact across a broader range of stroke profiles.

The potential of Brain Interchange™ was first demonstrated in the first study participant, who received the implant in July 2025. The system has since remained operational for nine months, with stable wireless performance and full functionality of both neural sensing and cortical stimulation maintained throughout.

"We now have three patients in the study, and each one adds a new dimension to what we can learn," commented **Jeffrey G. Ojemann, MD, Vice Chair and Professor of Neurological Surgery, University of Washington School of Medicine.**

"Nine months of reliable, fully implanted brain sensing and stimulation without compromise in performance is far from a given in this field," added **Dr. Martin Schuettler, CTO and Co-Founder of CorTec**. "We are now confident that the platform is ready for the demands of longer-term clinical use."

With TAP acceptance and Breakthrough Device Designation secured within two weeks, and a growing patient cohort demonstrating long-term implant stability, CorTec's Brain Interchange™ program is advancing on all fronts toward regulatory approval and broader clinical adoption in stroke motor rehabilitation.

About Brain Interchange™

Brain Interchange™ is CorTec's proprietary brain-computer interface platform, a fully implantable, wireless, bidirectional closed-loop system designed for long-term neural sensing and adaptive cortical stimulation of the cortex and deep brain areas. The investigational device has demonstrated over 500 days of continuous, stable operation (*Nature Scientific Data*, 2025) and is currently the only BCI platform to hold an FDA Breakthrough Device Designation specifically for therapeutic motor rehabilitation after stroke.

The platform's closed-loop architecture enables an entirely new therapeutic category: real-time, adaptive neuromodulation tailored to each patient's neural activity. Beyond stroke, Brain Interchange™ is being deployed in clinical and research programs addressing epilepsy (Mayo Clinic), treatment-resistant depression, and communication restoration for severely paralyzed patients (UMC Utrecht), establishing a multi-indication pipeline on a single, validated hardware platform.

Learn more at www.brain-interchange.com or follow the Brain Interchange on LinkedIn.

About CorTec

CorTec GmbH is a clinical stage neurotechnology company founded in 2010 in Freiburg, Germany. CorTec is developing Brain Interchange™, a fully implantable bidirectional BCI platform currently in FDA-authorized clinical evaluation in the United States. This makes CorTec the first and only European company to reach this stage. In April 2026, the device received both FDA Breakthrough Device Designation and admission to the FDA's Total Product Life Cycle Advisory Program (TAP) for stroke motor rehabilitation.

Alongside its proprietary BCI platform, CorTec operates a revenue-generating contract development and manufacturing (CDMO) business for advanced implantable components, serving leading neurotechnology companies worldwide. This dual model supports CorTec's platform development while scaling Europe's most vertically integrated neurotechnology capability.

CorTec is backed by a syndicate of strategic investors including High-Tech Gründerfonds, KfW, K&SW Invest, LBBW Venture Capital, Mangold Invest, M-Invest and Santo Venture Capital GmbH.

Learn more at www.cortec-neuro.com or follow CorTec on LinkedIn.

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