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Stimvia receives MDR certification for neuromodulation system

Stimvias URIS neuromodulation system. Credit: Stimvias

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By Shani Alexander

Stimvia s.r.o. recently secured Medical Device Regulation (MDR) certification for its Uris neuromodulation system to deliver both percutaneous tibial nerve stimulation (PTNS) and peroneal electrical transcutaneous neuromodulation (Peroneal eTNM) to treat lower urinary tract symptoms. “This dual capability is something we’re uniquely positioned to combine in clinical practice, setting a new benchmark in the field,” CEO Lukas Doskocil told *BioWorld*.

“We believe our technology is far superior to traditional treatments like sacral neuromodulation or onabotulinumtoxin injections,” Doskocil. “When you consider that there’s no significant difference in efficacy, but the risks of invasive procedures can prevent millions of patients from pursuing effective treatment, the choice becomes clear. Many people simply don't want to take the risk of something going wrong with invasive methods.”

Overactive bladder is a common condition affecting millions of people around the globe. It is characterized by symptoms of urinary frequency and urgency with or without incontinence associated with urgency. Urinary incontinence is the unintentional passing of urine.

Czech Republic-based Stimvia developed the Uris system that employs a non-invasive neuromodulation technique combined with closed-loop technology to treat overactive bladder. The system uses specially developed electrodes that stimulate the peroneal nerve, correcting brain imbalances and significantly reducing the severe and unpredictable urinary urgencies.

The stimulation is done in two separate phases. First, the patient is stimulated over the course of six to 12 weeks, daily, for 30 minutes each day. The device is equipped with closed-loop feedback, based on which it is possible to evaluate the effectiveness of stimulation and adjust the stimulation parameters to the specific patient.

In the second phase, the stimulation frequency is progressively reduced from daily to weekly with the goal of eventually only requiring a single stimulation session per month.

Stimvia claims to be the first company globally to introduce this innovative closed-loop neuromodulation system.

Stimvia CEO Lukas Doskocil

“Of all the innovations we’ve created, the Uris neuromodulation system stands out as something truly revolutionary,” said Doskocil. “We were the first pioneers to introduce a closed-loop neuromodulation system for non-invasive devices on a global scale. This is not just about being first – it’s about being at the forefront of a revolution in how technology and the human body can communicate to achieve remarkable results.”

According to Stimvia, a clinical effect was achieved in nearly 80% of patients treated with Uris which is comparable to the effectiveness of invasive sacral neuromodulation, an operation that carries its own risks. Furthermore, the treatment is associated with only minimal risks and side effects, which occurred in only 0.01% of cases.

The Uris system also received MDR certification for the mini-invasive percutaneous tibial nerve stimulation method, offering an alternative treatment for incontinence.

“The beauty of the Uris neuromodulation system is its versatility,” said Doskocil. “It is fully capable of delivering both percutaneous tibial nerve stimulation and our own closed-loop neuromodulation [Peroneal eTNM] for treating incontinence.”

“With our non-invasive approach, we’re aiming to become the new standard of care. The benefit-to-risk profile of the Uris neuromodulation system is unmatched, and we believe there’s nothing out there that offers a better solution. We’re not just providing an alternative – we’re reshaping what’s possible in treatment,” he said.

Validating the Uris neuromodulation system

The MDR certification from notified body TÜV SÜD, covering both treatment methods using the Uris neuromodulation system, confirms that the device, classified as a class IIa medical device, is designed and manufactured to be safe and effective.

The MDR certification means that the company has met all the rigorous requirements set forth by the regulation, said Doskocil. “This certification not only validates that our Uris neuromodulation system meets the highest standards of safety and efficacy but also grants us the right to affix the CE Mark to our product.”

“The CE mark, now that we’re compliant with MDR, symbolizes our commitment to quality and compliance, opening doors for us across Europe,” he added.

The company also received quality management system certification which guarantees that every part of Stimvia’s facility adheres to stringent standards, ensuring that the manufacturing process consistently produces high-quality products.

Targeting the overactive bladder market

The certification from the EU authorities is an important step in Stimvia’s journey to transform the current treatment of overactive bladder (OAB). According to Stimvia, the direct and indirect costs of OAB treatment in the EU and the U.S. are estimated at more than $117 billion per year.

The company said it aims to dominate a sizeable portion of this market and is just a step away from bringing its breakthrough technology to the U.S., enhancing the quality of life for millions of OAB patients.

Stimvia is currently working to navigate the regulatory landscape and secure FDA approval. “We’re committed to ensuring that every aspect of our process meets the rigorous standards set by the FDA, and we’re confident in our ability to achieve this milestone in the shortest time frame,” said Doskocil.

The company envisions entering the U.S. market in 2025, however, it will face competition. There are other companies providing solutions for overactive bladder including Bluewind Medical Ltd., Uro Medical Corp. and Medtronic plc.

Other companies are working on solutions to treat urinary incontinence including Affluent Medical SA is focused on developing Artus, which it claims is the first electronically activated sphincter to treat urinary incontinence in both men and women; Uromems SAS which is working on the Uroactive system, the first smart automated artificial urinary sphincter (AUS) device to treat stress urinary incontinence; and Amber Therapeutics Ltd. which is developing an implantable closed-loop bioelectrical therapy to treat women suffering from mixed urinary incontinence.

“What makes us truly unique is not just the innovation – it’s the intellectual property and the experience behind it,” said Doskocil. “We hold more than 100 patents globally and have established prior art in this space. No one else has the depth of knowledge or the same level of expertise in closed-loop neuromodulation. We’ve set the standard, and we’re pushing the boundaries of what’s possible.”

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