

Stimvia Plans to Enter Multi-Billion Dollar Neuromodulation Market in the USA: Secures Prestigious MDR Certification and Opens the Door to Reimbursement Globally

August 27th, 2024 — [Stimvia](#), a pioneering medical technology company, is poised to make a significant impact on the multi-billion dollar neuromodulation market in the United States with its innovative [URIS®](#) device — the first non-invasive closed-loop neuromodulation system to treat overactive bladder (OAB) without surgery or drugs. The URIS® device has recently secured the prestigious MDR (Medical Device Regulation) certification from TÜV SÜD covering Stimvia's groundbreaking non-invasive neuromodulation technique (eTNM®) as well as the mini-invasive percutaneous tibial nerve stimulation (PTNS) method. The certification allows Stimvia to enter the lucrative European market and opens doors to global reimbursement opportunities.

Unlocking a Multi-Billion Dollar Market

The Czech company Stimvia, located in the heart of Europe, has come to the market with its URIS® device after several years of research and three clinical trials. The device recently received the prestigious MDR (Medical Device Regulation) certification from the German notified body TÜV SÜD. **This achievement unlocks the company's path to the overactive bladder treatment market, where the current cost of neuromodulation treatment is nearly \$1 billion per year only in the USA. Overall, the direct and indirect costs of OAB treatment in the EU and the USA are estimated at more than \$117B per year.** Stimvia aims to dominate a significant portion of this market and is just a step away from bringing its breakthrough technology to the US, enhancing the quality of life for millions of OAB patients. This milestone marks an important step in Stimvia's journey to transform the current treatment of OAB and create a multi-billion-dollar market.

The Technology Capable of 'Hacking' the Brain

Stimvia's URIS® device employs a groundbreaking non-invasive neuromodulation technique (eTNM®) combined with closed-loop technology. Specially developed electrodes stimulate the peroneal nerve, correcting brain imbalances and significantly reducing the severe and unpredictable urinary urgencies experienced by OAB patients. In addition, 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. *"We are proud to be the first company globally to introduce this innovative closed-loop neuromodulation system,"* says Lukas Dorskocil, CEO of Stimvia. **Clinical studies show URIS® technology as one of the most effective treatments for OAB, which affects approximately 40 million people in the USA and 500 million worldwide.**

The PTNS treatment method is becoming more precise and the procedure simpler

Additionally, Stimvia has received MDR certification for the mini-invasive percutaneous tibial nerve stimulation (PTNS) method, offering an alternative treatment for incontinence. **With this certification, Stimvia has become only the third company in the world, and the first in Europe, to possess the**

certification for this technology. This achievement places the company alongside industry giants like Medtronic and Laborie and also **paves the way for Stimvia to enter the American market and brings the company closer to obtaining FDA 510(k) clearance, a critical step toward launching in the US.**

The PTNS method has also become much more precise after being combined with the URIS® device, and its application, which involves inserting a small stimulation needle into the inner side of the patient's ankle, has become more comfortable for both the doctor and the patient.

"Thanks to obtaining MDR certificates for the PTNS method, we enter the system of reimbursement by health insurance companies in Europe and in the USA as well. We already have the first devices in the offices of Czech urologists. At the same time, we are already in the process of delivering our devices to countries in Europe, such as Italy, France, Spain, Denmark, the Netherlands, and the UK," says Dorskocil, adding: "While the PTNS method is recognized globally in the healthcare system, our non-invasive technology is also gaining attention due to the excellent results and high quality of our clinical trials."

Strategic Position and Future Growth

According to clinical studies, URIS®, with its non-invasive technology, ranks among the most effective methods in the fight against OAB. **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. Moreover, the treatment is associated with only a minimal amount of risks and side effects, which occurred in only 0.01% of cases. It is this **excellent balance between clinical effectiveness and negligible risk of adverse effects that makes this treatment unique.**

Stimvia is now capitalizing on its strong research in the field of OAB and its strategic market position as a pioneer in non-invasive neuromodulation. This position is further reinforced by a robust intellectual property portfolio, which includes over 100 international patents. The company's advanced technologies have been validated through rigorous clinical studies, demonstrating significant efficacy in treating chronic conditions like OAB.

About Stimvia

Stimvia is a leader in the field of medical technology, specialising in the development and commercialization of innovative neuromodulation therapies for chronic diseases. The company's flagship product, URIS®, employs a groundbreaking method of peroneal neuromodulation, representing the first non-invasive technique for deep brain stimulation. Stimvia's technologies are globally protected and certified by prestigious institutions, including TÜV SÜD.

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