Press Release

Medeon Announces Positive Clinical Results for XFLO Minimally Invasive BPH Treatment Device

TAIPEI, January 27, 2021 – Medeon Biodesign, Inc. (TPEx: 6499), a Taiwan publicly traded medical device company, is pleased to announce positive interim results of the EXPANDER-1 Clinical Study for its flagship product the XFLO™ Expander System, an innovative, minimally invasive Benign Prostatic Hyperplasia (BPH) treatment solution. XFLO offers a reversible and office-based treatment option for patients who are seeking immediate relief from lower urinary tract symptoms (LUTS) caused by BPH without compromising sexual function.

The XFLO Expander System is designed to provide patients with immediate relief BPH-related symptoms (LUTS) by placing an expander implant in the prostatic urethra using a low-profile delivery catheter and a standard flexible cystoscope. The XFLO Expander System opens the prostatic urethra that is narrowed due to the enlargement of the prostatic lobes. A unique feature of the XFLO Expander procedure is that it is designed to be completely reversible and preserves future treatment options, if needed. The XFLO Expander System may be easily retrieved in an office setting using standard flexible cystoscopes and the XPRO Retrieval Sheath. The EXPANDER-1 clinical study is an ongoing multinational study that is being conducted in Australia, Republic of Georgia, Canada, and Taiwan. To date, the study has enrolled and treated 32 patients using the XFLO Expander and the XPRO Retrieval sheath. Early data from this study has demonstrated the device can be safely deployed and retrieved after implantation following a dwell time of up to 6 months. The EXPANDER-1 study confirms that the procedure is a safe and minimally invasive BPH treatment that can potentially avoid post-procedure catheterization and preserves sexual function. In addition, the XFLO Expander System was demonstrated to be effective at providing immediate symptom relief (2 weeks post-implant) with 40% reduction in IPSS (International Prostate Symptom Score) for a 6 months dwell time (N=14). Efficacy continues to remain at least 6 months post-retrieval, indicating a promising minimally invasive solution to achieve patency effect of one year post-treatment. Long-term follow-up is on-going in order to obtain additional safety and efficacy outcome measures.

“Currently available BPH medications are often insufficiently effective or involve side effects, including but not limited to sexual dysfunction and compromised quality of life, which result in 66% of patients discontinuing medication within 1 year. Surgical treatments are known to not only involve bleeding and temporary catheterization, but also result in permanent tissue damage and irreversible side effects including ejaculatory dysfunction. There is a strong need for an alternative minimally-invasive solutions that offer rapid relief from BPH/LUTS and have no risk of urinary incontinence or impact on sexual function,” said Dr. Henry Woo, a world-renowned urological surgeon and Professor of Surgery at the University of Sydney, Australia.

“The early clinical results indicate the XFLO Expander System could be a promising new minimally-invasive therapy for BPH patients. It can provide rapid and effective relief from lower urinary tract symptoms, without compromising sexual function. The reversible nature of the solution can also preserve future treatment options for patients, if needed.“ said Dr. Chi-Ping Huang, Director of Urology at China Medical University Hospital in Taichung, Taiwan.

Dr. Yue-Teh Jang, Chairman and CEO of Medeon Biodesign stated, “Our goal is to address the significant unmet need for treating the 70+ million global patients living with BPH”, he continued, “We are very pleased with the early results of our EXPANDER-1 clinical study, and the feedback obtained from investigators. We will continue to study and monitor the long-term safety and effectiveness of the XFLO Expander procedure with the focus of bringing this novel BPH therapy to market to treat patients suffering from BPH worldwide.”

About Medeon Biodesign and MedeonBio

Medeon Biodesign (TPEx: 6499) is a publicly traded company located in Taipei, Taiwan, and currently listed on Taipei Exchange. MedeonBio, based in Sunnyvale, California, is 100%-owned US subsidiary of Medeon Biodesign. The company focuses on the development of medical devices for minimally invasive surgeries to treat diseases in large patient populations such as Urology, Cardiovascular, Orthopedic, and Ophthalmology. For more information, please visit www.medeonbio.com/en.

About The EXPANDER-1 Clinical Study (NCT03758222)

The EXPANDER-1 clinical study is a First-in-Human/Feasibility, open-label, prospective clinical trial being conducted outside the United States in Australia, the Republic of Georgia, Taiwan, and Canada. The objective of this study is to evaluate the safety and feasibility using the XFLO Expander system to treat patients with lower urinary tract symptoms (LUTS) secondary to urinary outflow obstruction from benign prostatic hyperplasia. The XFLO implant is retrieved using the XPRO Retrieval Sheath. The XFLO Expander System and the XPRO Retrieval Sheath are investigational products not currently approved in the United States, Canada, Australia, or Taiwan. Their use is limited to investigational use in clinical trials.

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