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Renovia Announces FDA 510(k) Clearance of Next-Generation *leva*® Pelvic Digital Therapeutic

Next-Generation leva® Digital Therapeutic Includes Patented Technology and Leverages Peer-Reviewed Mechanism of Action of Current leva® Digital Therapeutic

Boston, MA – November 25, 2019 – Renovia Inc. ("Renovia"), a company dedicated to discovering and delivering first-line digital therapeutic and diagnostic device and app technologies for women with pelvic floor disorders, today announced U.S. Food and Drug Administration (FDA) 510(k) clearance for the next-generation *leva*® Pelvic Digital Therapeutic for the strengthening of pelvic floor muscles and the treatment of stress, mixed and mild to moderate urgency urinary incontinence (UI) in women.

The next-generation *leva*® Digital Therapeutic utilizes Renovia's patented movement-based sensor and app technology[1] to provide women real-time feedback as they perform their pelvic floor muscle exercises. The new *leva*® Digital Therapeutic is based on the same mechanism of action and sensor technology found in current-generation *leva*® Digital Therapeutic that has been shown to provide statistically significant improvement in (1) objective pelvic floor muscle (PFM) performance measures, (2) patient-reported UI symptom severity, and (3) condition-specific quality of life.[2]

"We are thrilled to receive FDA clearance for the next-generation *leva*® Digital Therapeutic," said Marc Beer, Co-Founder, Chairman and Chief Executive Officer of Renovia. "Over the past two years, the Renovia team has taken the peer-reviewed mechanism of action of the existing *leva®* device and completely reimagined it in a patient-centric form factor. The next-generation *leva*® combines our clinically-established and patented technology with a new discreet form factor and a completely redesigned app interface."

Renovia recently completed a multi-center, pilot randomized controlled trial (RCT) using the next-generation *leva*® Digital Therapeutic device. The study included sixty (60) subjects, with the control group performing traditional Kegel exercises. Despite being a sixty (60) subject pilot study, the study found statistically better results among *leva®* users.

"We look forward to announcing and publishing the results of our pilot RCT in the coming months," noted Samantha Pulliam, MD, Chief Medical Officer at Renovia. "In the meantime, we're using those results to finalize the design of a larger multi-center RCT that we will launch in the first half of 2020. Renovia is focused on improving the standard of care for female pelvic floor disorders through innovative products supported by world-class clinical evidence. FDA clearance of the next generation of the *leva*® Digital Therapeutic is one of many milestones that we believe will allow us to improve care for the millions of women who experience UI and other pelvic floor disorders."

UI affects an estimated 20 million women in the U.S. alone. UI can have a negative impact on quality of life and lead to potentially severe medical conditions. Despite this prevalence and known adverse effects on women's health, UI is often underreported by women and not recognized by clinicians. Early intervention has been shown to resolve or reduce symptoms, improve immediate and long-term condition-specific quality of life, and limit the need for more complex and costly treatments, such as surgery or long-term medication.

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[1] U.S. Patent No. 10,470,862.

[2] Rosenblatt P, McKinney J, Rosenberg RA, Iglesias RJ, Sutherland RC, Pulliam SJ. Evaluation of an accelerometer-based digital health system for the treatment of female urinary incontinence: A pilot study. Neurourology and Urodynamics. 2019;1-9. https://doi.org/10.1002/nau.24097

Jessica McKinney, PT, Renovia's Vice President of Medical Affairs and Clinical Advocacy, stated, "We are thankfully seeing increased attention being paid to women's health issues, including pelvic floor health. Last year's release of the ACOG (American College of Obstetricians and Gynecologists) led WPSI (Women's Preventive Services Initiative) opinion reinforcing the importance of annual screening for urinary incontinence[3] is a great example."

"Pelvic floor muscle exercises are the widely accepted first-line conservative treatment for pelvic floor disorders including stress, urgency, and mixed UI," added McKinney. "Unfortunately, many women have trouble identifying and contracting the correct muscles when performing these exercises, and remembering to perform the exercises regularly can be challenging. *leva®* helps women know whether they are performing their PFM exercise correctly and provides engaging reminders about missed exercises, meaning it can fit perfectly into the care pathway of women who want to avoid surgery or the possible side-effects of medications, including serving as a valuable adjunct to supervised care with a physical therapist or other healthcare provider. I couldn't be more excited about helping bring products like the next-generation *leva®* Digital Therapeutic to market."

Since its founding in 2016, Renovia has been committed to developing a product pipeline with the therapeutic and diagnostic potential to have a profound positive impact on the lives of women. Renovia's FDA-cleared devices have a targeted mechanism of action that isolates and directs optimal movement of pelvic floor muscles. These devices and the full product pipeline all leverage state-of-the-art app and data management technology to provide precise, cost-effective treatment of weakened pelvic floor muscles in real-time, while collecting actionable compliance and progress data on women's pelvic health.

Commercial Availability of Next-Generation *leva®* Digital Therapeutic

The next-generation *leva®* Digital Therapeutic is expected to be released for sale in the Spring of 2020. The current-generation *leva®* Digital Therapeutic remains commercially available in the US for the strengthening of pelvic floor muscles and the treatment of stress, mixed and mild to moderate urgency urinary incontinence in women.

Important Safety Information for Current-Generation and Next-Generation *leva®* Digital Therapeutic

The *leva®* Pelvic Digital Therapeutic is intended for the strengthening pelvic floor muscles; and rehabilitation and training of pelvic floor muscles for the treatment of stress, mixed and mild to moderate urgency urinary incontinence in women.

Treatment with the *leva®* Digital Therapeutic is by prescription and is not for everyone. Please talk to your prescriber to see if the *leva®* Digital Therapeutic is right for you. Your prescriber should discuss all potential benefits and risks with you. Do not use the *leva®* Digital Therapeutic while pregnant, or if you think you may be pregnant, unless authorized by your doctor. For a complete summary of the risks and instructions for the *leva®* Digital Therapeutic, see its Instructions for Use available at Renovia's website.

About Renovia

Renovia Inc.™ was formed to develop and commercialize products for better first-line diagnosis and treatment to improve the condition-specific quality of life for millions of women with pelvic floor disorders. Renovia's technology enables treatment via precise visualization of pelvic movement in real time during pelvic floor muscle training, while monitoring usage and progress over time. As a women's health

[3] O'Reilly NO, Nelson HD, Conry JM, Frost J, Gregory KD. Screening for Urinary Incontinence in Women : A Recommendation from the Women's Preventive Services Initiative. Annals of Internal Medicine 2016.https://doi.org/10.7326/M18-0595

organization, Renovia is in pursuit of scalable and cost-effective care for pelvic floor disorders delivered through the power of digital health. For more information, please visit here.

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