PRESS RELEASE
For immediate release

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FDA Grants DeNovo Clearance to Atlantic Therapeutics for INNOVO® Therapy Device to Treat Stress Urinary Incontinence

- INNOVO® is the first ever transcutaneous electrical stimulator cleared by the FDA, offering US women a safe, clinically effective and non-invasive choice to treat stress urinary incontinence
- In its pivotal multi-centre randomized controlled clinical trial, 87.2% of INNOVO® users were dry or mild after a 12-week treatment period[1]
- INNOVO® is a novel wearable device, that may be prescribed as a front-line therapy to those suffering stress urinary incontinence, or as a second line therapy to those that have previously failed physical therapy (in the form of supervised or unsupervised pelvic floor exercises, also known as Kegel exercises)

Atlantic Therapeutics, a global manufacturer of innovative, garment-based pelvic floor muscle strengthening and nerve stimulation products, announced today (12.11.18) that the U.S. Food and Drug Administration (FDA) has granted a DeNovo clearance for its INNOVO® therapy device, an externally worn electrical muscle stimulator for the treatment of stress urinary incontinence in adult females.

FDA Approval Supported by Results from Two Multi-Centre Randomized Controlled Clinical Trials

INNOVO® is the first transcutaneous electrical stimulation continence device to be cleared by the FDA, following results of two randomized controlled trials (RCTs) demonstrating it to be an effective and low-risk device for the treatment for stress urinary incontinence (SUI) in adult females. Atlantic Therapeutics presented key data from its pivotal US trial showing 87.2% of patients were dry or mild of after a 12-week treatment period1, with 93% of patients experiencing improvement in just 4 weeks1. This follows the presentation of data from an earlier sham-controlled RCT conducted in Europe that demonstrated significant improvement across all study endpoints[2].

“For the first time, physicians in the U.S. can offer their patients a safe, clinically effective, noninvasive home-based treatment” said Steve Atkinson, CEO, Atlantic Therapeutics.

“INNOVO® therapy is a compelling treatment option for all those women who today simply suffer in silence from stress urinary incontinence”

With an estimated one third of all U.S. females affected by SUI[3], the market potential for INNOVO® is significant, making this big news for the Galway, Ireland, based medical device manufacturer. With recent widespread reports of mesh surgery complications, this is an ideal PRESS RELEASE For immediate release 13 November 2018 AT FDA Approval INNOVO – D6 – not for distribution 2/3 time to offer a non-invasive option. INNOVO® has an excellent safety record to date, with over 1.5 million therapy sessions delivered by INNOVO® in Europe and no reported device related complications.

"INNOVO® is a major breakthrough for the millions of women who have to deal with the emotional and physical daily burden of incontinence," said Gordie Nye, Chairman of Atlantic Therapeutics, "INNOVO® is the active solution for U.S. women who otherwise face a life wearing absorbent pads."

Mary Lynne Van Poelgeest-Pomfret, President of the World Federation of Incontinence Patients (WFIP) said, "WFIP is excited to hear that INNOVO® has received FDA clearance, enhancing treatment choice for U.S. patients. We are confident it will change people's lives; INNOVO® therapy is fully supported by the WFIP."

INNOVO® has been well received by many U.S. organisations and healthcare professionals concerned with the welfare of patients with incontinence.

"INNOVO® offers a new frontline therapeutic option for the millions of American women living with stress urinary incontinence, and in a significant group could delay or prevent the need for higher risk surgery or medical intervention," said Elizabeth LaGro, Vice President, The Simon Foundation for Continence.

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References

1. ICS 2018, POSTER NO. 235, Roger Dmochowski, Vanderbilt University, Catherine M. Lynch, University of South Florida, Mitchell Efros, AccuMed Research Associates, Linda Cardozo, King's College Hospital, London.

2. IUGA 2018, Poster NO. 135, S.Soeder, German pelvic Floor Center Berlin, T. Fink, Pelvic floor Center, Berlin–Lichtenberg, M. Goetze, Hospital Brandenburg, G. Neymeyer, Charite Medical University, Berlin R.Tunn German pelvic Floor Center Berlin

3. The Urology Care Foundation (2018) Available at: [http://www.urologyhealth.org/] (Accessed: 24th August 2018)