Pelvic Health
Clinical Summary
A Prospective Study to Evaluate Efficacy with the NURO
Percutaneous Tibial Neuromodulation System in
Drug Naïve Patients with OAB. AUA 2018 Late breaking abstract.

CONTEXT FOR STUDY
Many published studies provide evidence supporting the safety and efficacy of Percutaneous Tibial Neuromodulation (PTNM) for OAB patients¹,²,³, however these studies included patients who had previously used OAB medications and received PTNM therapy delivered by a different (but equivalent) device other than the NURO™ device.

RESET is the first study to establish clinical evidence on the NURO™ device and to study PTNM on patients who had not attempted medical management for OAB. This sets RESET apart from other PTNM studies and establishes that the NURO™ therapy can significantly reduce UI episodes for drug-naïve patients with OAB.

STUDY OVERVIEW
- Multicenter, single arm (all patients received NURO™ PTNM), prospective study sponsored by Medtronic
- Patients with OAB received 12 weekly PTNM sessions with the NURO™ system
- Study assessed Voiding Diaries, Quality of Life and other Patient Reported Outcomes, and Safety⁴
- Analyses were based on patients who had data at baseline and follow-up visits

PATIENT PROFILES
- 120 patients, none of which had tried OAB medication prior to enrollment
- Mean Age: 64.8
- Mean duration of OAB diagnosis: 3.4 years
- Gender mix: 86% female

RESULTS
Change in Urge Urinary Incontinence Episodes (UIIE) /day
- Urge incontinence (UI) improvement (reduction in UIIE) was significant vs baseline at the first follow-up visit and remained significant at each subsequent visit through 12 weeks
- Subjects with urinary frequency (UF) had 11.5±2.9 voids/day at baseline with a reduction of 1.7±2.5 voids/day after 12 weeks (p<0.0001)
- Most common AEs: medical device site pain (3.3%, 4/121*) and extremity pain (3.3%, 4/121)

Baseline 3.5 UIIE/day. Error bars 95% CI. ***p<0.0001.

*While 120 patients met criteria for efficacy analyses, 121 patients were treated and included in safety analyses.
AUTHOR CONCLUSIONS
In this study\(^4\), PTNM using the NURO™ device was shown to be an effective and safe treatment for drug-naïve patients with OAB.

FURTHER RELEASE OF RESET DATA
Additional results from the RESET study will be presented at other upcoming conferences.

TAKE HOME MESSAGES
- RESET represents the first NURO™ clinical study, establishing clinical data on the NURO™ device
- RESET study subjects were drug-naïve, meaning they tried PTNM therapy without first attempting medical management. This is what sets RESET apart from most other PTNM studies
- UI improvement (reduction in UUIE) was significant vs baseline at the first follow-up visit and remained significant at each subsequent visit through 12 weeks

OVERVIEW OF PREVIOUS PTNM STUDIES
Previous studies of PTNM, also called Percutaneous Tibial Stimulation (PTNS) in these studies, did not focus on drug-naïve patients. Additionally, the NURO™ device was not used in these studies; however, since NURO™ delivers equivalent stimulation therapy as the device used in the studies, the user can expect similar performance.

- **SUmiT Study\(^1\)**
  - **Purpose**: compare PTNS to sham in OAB patients
  - **Method**: 220 patients randomized 1:1 to receive 12 weekly sessions of either PTNS or sham
  - **Efficacy**: PTNS showed superior efficacy in reduction of incontinence and urgency episodes vs sham, and significantly more PTNS-treated patients reported moderate or marked response vs. sham
  - **Safety**: 5% of PTNS subjects reported mild or moderate treatment related adverse events
  - **Conclusion**: PTNS is safe and effective in treating OAB symptoms

- **ORBiT Study\(^2\)**
  - **Purpose**: compare PTNS to extended-release tolterodine in OAB patients
  - **Method**: 100 patients randomized 1:1 to receive 12 weeks PTNS vs Tolterodine
  - **Efficacy**: Improvement in OAB symptoms was statistically significant for both PTNS and Tolterodine, with no statistically significant difference in therapy response between groups
  - **Safety**: Treatment-related adverse events were reported in 16.3% of PTNS subjects and 14.3% of tolterodine subjects
  - **Conclusion**: PTNS is safe with effectiveness comparable to that of pharmacotherapy

- **STEP Study\(^3\)**
  - **Purpose**: evaluate the long-term PTNS efficacy and safety for OAB after 3 years
  - **Method**: 29 SUmiiT trial patients received an average of 1.1 PTNS treatments per month for 36 months after the initial 12-week SUmiiT trial\(^1\)
  - **Efficacy**: 77% of initial responders had long-term, sustained efficacy at 3 years
  - **Safety**: Two mild treatment-related adverse events of bleeding at the needle site were reported in the same participant
  - **Conclusion**: PTNS is an effective, long term treatment for patients with OAB
REFERENCES

4. ClinicalTrials.gov NCT02857816

Please contact Medtronic Medical Affairs if you would like to discuss this information in more detail.

Indication for Use: Medtronic NUROTM Percutaneous Tibial Neuromodulation is intended to treat patients with overactive bladder and associated symptoms of urinary urgency, urinary frequency, and urge incontinence. Contraindications: Do not use on patients with pacemakers or implantable defibrillators, patients prone to excessive bleeding, patients with nerve damage that could impact either percutaneous tibial nerve or pelvic floor function, or on patients who are pregnant or planning pregnancy. Warnings/Precautions/Adverse Events: Do not use if the skin in the area of use is compromised. Exercise caution for patients with heart problems. Adverse events are typically temporary, and include mild pain, minor inflammation and bleeding near treatment site.

For full prescribing information, please call Medtronic at 1-800-328-0810 and/or consult Medtronic’s website at professional.medtronic.com/NURO. Product technical manual must be reviewed prior to use for detailed disclosure.

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