Cala Announces Data from Multiple Clinical Studies Demonstrating Effective Outcomes of Transcutaneous Afferent Patterned Stimulation (TAPS) Therapy in Essential Tremor (ET) Patients

SAN MATEO, CA – January 9, 2024 – Cala, the bioelectronic medicine leader, today announced the results from multiple clinical studies, further strengthening evidence supporting positive outcomes for patients using Cala TAPS Therapy in ET.

A randomized pragmatic trial by CVS Health found that adding Cala TAPS therapy to standard of care (SOC) improved outcomes over SOC alone. The study recruited patients from the database of a large health insurer (AETNA) and represents the largest prospective device study run in essential tremor to-date (N = 310). The study found significant improvements in tremor power (measured by motion sensors) and Bain & Findley Activities of Daily Living (BF-ADL) upper limb scores over one month of TAPS compared to SOC alone, demonstrating that TAPS is a safe and effective treatment option for patients with ET.
https://tremorjournal.org/articles/10.5334/tohm.798

A large real-world evidence (RWE) analysis found that patients using Cala TAPS therapy achieved consistent relief over multiple years of use. This study examined the real-world application of Cala TAPS therapy by analyzing usage (N = 1223) and effectiveness data (N = 808) collected from device logs and voluntary patient surveys. Consistent with previous findings, the study found Cala TAPS Therapy effectively reduces tremor with an average reduction in tremor power (measured by motion sensors) of 64%. Further, the study reported consistent usage with no significant habituation over long term use (up to 3.4 years).
https://tremorjournal.org/articles/10.5334/tohm.775

A secondary analysis of previously published studies assessed TAPS response in patients with high unmet need and patients who observed benefit from TAPS therapy during their first month of use (early responders). The study found significant improvement over sham in the high unmet need subgroup (severe tremor, non-responsive to medication, age ≥65 years) of a randomized controlled study (N = 47, $P < 0.03$) and significant improvements over multiple months of use in the high unmet need (N = 138, $P < 0.001$) and early responder cohort (N = 51, $P < 0.001$).
https://www.tandfonline.com/doi/abs/10.1080/17434440.2023.2274604

“We are excited about the growing body of evidence demonstrating that TAPS improves patient outcomes in real-world settings,” said Kate Rosenbluth, PhD, Co-President and Chief Scientific Officer, Cala Health. “With these latest publications,

TAPS has now been assessed in nearly 2,000 ET patients and with use extending beyond 3 years. TAPS addresses the large treatment gap between medications and surgery for ET patients struggling with activities of daily living such as eating, drinking writing and self-care."

"Cala is a contracted provider with major national and regional health plans for essential tremor including both commercial and Medicare Advantage members," said Deanna Harshbarger, Co-President and Chief Product Officer, Cala Health. "The Cala System is covered by the Veterans Affairs (VA) Health System at no cost to VA beneficiaries. With these expanded publications, Cala will continue working tirelessly on behalf of patients with ET to secure additional coverage and reimbursement."

About Cala®

Cala Health is a bioelectronic medicine company transforming the standard of care for chronic disease. The company's wearable neuromodulation therapies merge innovations in neuroscience and technology to deliver individualized peripheral nerve stimulation, and its direct-to-home digital durable medical equipment (DME) platform is reshaping the delivery of prescription therapies. Cala Health's products are the only FDA-cleared, clinically validated noninvasive devices for the relief of hand tremors, allowing patients with essential tremor to return to the moments that matter. New therapies are under development in neurology, cardiology, and psychiatry. Founded in 2014, the company is headquartered in the San Francisco Bay Area and backed by leading investors in both healthcare and technology.

The Cala kIQ device is indicated to aid in the temporary relief of hand tremors in the treated hand following stimulation in adults with essential tremor. The Cala kIQ device is indicated to aid in the temporary relief of postural and kinetic hand tremor symptoms that impact some activities of daily living in the treated hand following stimulation in adults with Parkinson's disease. The Cala kIQ device delivers Transcutaneous Afferent Patterned Stimulation (TAPS) therapy.

Caution: Federal law restricts this device to sale by or on the order of a physician. Prior to use, refer to the product labeling for complete product instructions for use, contraindications, warnings, and precautions at https://calahealth.com. ###

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