

Cala Health Reports New Data Demonstrating Increasing Prevalence of Essential Tremor (ET) and High Rates of Depression and Anxiety in Patients with ET

– Data presented at the Virtual ISPOR Europe 2020 conference underscore the growing need for ET treatment and support Cala Trio™ as a safe and effective ET therapy in real-world settings –

– Essential Tremor prevalence has shown consistent increase over eight consecutive years –

Burlingame, CA – November 16, 2020 -- Cala Health, Inc., a bioelectronic medicine company developing wearable therapies for chronic disease, today reported data demonstrating the increasing prevalence of essential tremor (ET) from 2010 to 2018; a high rate of depression and anxiety in patients with ET; and the safety and efficacy of Cala Trio when used in a real-world setting to treat ET. The data are being reported today in three abstracts at the Virtual ISPOR Europe 2020 conference. ISPOR is the leading professional society for health economics and outcomes research globally.



“The findings demonstrating the increasing prevalence of ET and the high proportion of these patients who have anxiety and depression as comorbidities, underscore the need for safe, effective and easy-to-use therapies that allow patients with ET to adhere to their treatment regimens and achieve maximum therapeutic benefit,” said Patrick McCartney, Executive Director of the International Essential Tremor Foundation. “Despite the fact that ET is the most prevalent tremor disorder, affecting an estimated ten million people in the United States alone, the most common approach to therapy is the off-label use of medications approved for other indications. Patients with ET need therapies specifically designed to address their hand tremors and mitigate the negative effects that ET often has on their quality of life.”

An analysis of claims data from 819,661 patients with commercial (median age 55 years) or Medicare (median age 74 years) health insurance with at least one claim for ET in 2018 found that the ET prevalence rate among these populations increased at an annual growth rate of 6.27% from 2010 to 2018. Annual growth rates were 7.29% and 2.05% for the Medicare and commercial health insurance populations, respectively.

A separate analysis of claims data evaluated drug utilization, initiation of treatment at diagnosis, and the proportion of patients with or without ET who also had mental health conditions among patients with commercial or Medicare health insurance. Although 68% of patients newly diagnosed with ET received a prescription for pharmacologic therapy, 32% failed to fill a prescription within 24 months of diagnosis. The study also found that a higher percentage of patients with ET compared with patients without ET also received a diagnosis of depression (31.7% vs. 11.0% for patients with commercial coverage; 27.6% vs. 14.2% for patients with Medicare coverage) or anxiety (39.3% vs. 14.8% for patients with commercial coverage; 34.1% vs. 14.4% for patients with Medicare coverage) in the same period. These findings demonstrate that many patients with ET remain untreated, and the findings on depression and anxiety are consistent with prior reports in the literature as common comorbidities for patients with ET.

“The data presented at ISPOR are a stark reminder that ET is the most prevalent and growing tremor disorder, and it is also associated with anxiety and depression that can further reduce patients’ quality of life,” said Kate Rosenbluth, Ph.D., Founder and Chief Scientific Officer of Cala Health. “We are pleased to share real-world evidence on the safety, efficacy, and ease of use of Cala Trio in treating action tremors in the hands of patients with ET.

The final abstract containing real-world evidence of Cala Trio, extends data previously reported at the MDS Virtual Congress in September 2020 and shows that in therapy sessions following their most severe tremors, 90% of the 178 analyzed patients experienced at least a two-fold improvement (50% reduction) in tremor power. Additionally, 57% of all patients experienced at least a two-fold improvement in tremor power over all sessions. Of the 48 patients who completed a post-market survey, 69% reported improvement in their ability to eat, drink, and write, and 48% reported improvement in quality of life. Over half (56%) of patients indicated preference for Cala Trio to existing pharmaceutical and surgical options for ET treatment.

Cala Trio, a non-invasive targeted therapy that reduces hand tremors, is currently FDA-cleared for essential tremor. [Earlier this year](#), the FDA granted Breakthrough Device Designation to Cala Trio for the treatment of action tremors in the hands of adults with Parkinson's disease. The Company initiated the next clinical trial evaluating the therapy in the treatment of action hand tremors in patients with Parkinson's disease in early November.

ISPOR Data Presentations

Prevalence of Essential Tremor Among Patients with Commercial or Medicare Health Insurance in the United States from 2010-2018 (Abstract #PND75)

Real-World Burden of Comorbidities Along with Drug Utilization in United States Patients with Essential Tremors (Abstract #PND78)

Real-World Evidence for Symptomatic Relief in Essential Tremor Using Transcutaneous Afferent Patterned Stimulation Therapy (Abstract #PND112)

About Essential Tremor (ET)

Essential Tremor (ET) is the most prevalent tremor disorder and one of the most common neurological disorders, affecting an estimated seven million people in the United States. It is a chronic condition that causes involuntary and rhythmic shaking and typically worsens over time. ET can affect almost any part of the body, but the trembling most often occurs in the hands, making everyday activities such as eating, writing, or getting dressed extremely difficult. ET is often confused with Parkinson's disease, although it is eight times more common. A key difference is that hand tremors caused by ET happen with goal-directed movement (with intention), whereas Parkinson's disease tremors occur mostly at rest. Current ET treatments include mostly off-label use of medications or brain surgery.

About Cala Trio™

Cala Trio™ is the first non-invasive targeted therapy that reduces hand tremors for adults living with Essential Tremor (ET). Prescription therapy is a simple, wrist-worn device that is calibrated to treat a patient's unique tremor symptoms. When activated,

Cala Trio gently stimulates the nerves in the wrist to disrupt the tremulous activity in the brain, without the need for invasive brain surgery or medication. The easy-to-use and effective Cala Trio can be prescribed through an in-person consultation or telemedicine appointment. Therapy is conveniently delivered to the patient's home, and Cala Health educates patients based on how they learn—phone, video, user portal.

About Cala Health, Inc.

Cala Health, an award-winning bioelectronic medicine company, is transforming the standard of care for chronic disease while putting patients first. The Company's wearable neuromodulation therapies merge innovations in neuroscience and technology to deliver individualized peripheral nerve stimulation, and its vertically integrated commercial model is reshaping the delivery of prescription therapies. Cala Health's lead product, Cala Trio™, is the only non-invasive, wrist-worn prescription therapy for essential tremor. New therapies are under development in neurology, cardiology, and psychiatry. Cala Health is headquartered in the San Francisco Bay Area and backed by leading investors in both healthcare and technology. For more information, visit CalaHealth.com.

About The International Essential Tremor Foundation

Founded in 1988, the International Essential Tremor Foundation (IETF) is the leading organization in the world dedicated to people affected by essential tremor (ET). Its mission is to provide the ET community worldwide through awareness, education, support and research. To date, the IETF has awarded \$900 million in research grants to fund numerous promising studies in the search for the cause of ET. Each year, it hosts numerous community awareness events across the U.S. to provide those affected with the basic knowledge necessary to become their own advocate when seeking treatment. The IETF also provides assistance to a vast network of support groups around the world. To learn more about essential tremor and the IETF, visit www.essentialtremor.org.

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