Click Therapeutics Receives FDA Breakthrough Device Designation for Prescription Digital Therapeutic to Treat Episodic Migraine

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NEW YORK--(BUSINESS WIRE)--Click Therapeutics, Inc. ("Click"), a leader in Digital Therapeutics™ as prescription medical treatments, today announced that it has received Breakthrough Device Designation from the U.S. Food and Drug Administration (FDA) for CT-132. Click's CT-132 prescription digital therapeutic is under development as an adjunctive preventive treatment for episodic migraine in patients aged 18 years and older.

Migraine is a complex and debilitating condition that affects more than 47 million Americans,[1] and is the second leading cause of years lived with a disability.[2] For those living with migraine, attacks unfold over hours to days and negatively impact many domains including employment, educational attainment, and relationships.[3] Despite its prevalence, migraine remains a disorder with high unmet need due to incomplete remission and lack of access to specialty care.

The Breakthrough Devices Program is intended for devices that have potential to provide for more effective treatment over existing standard of care for life-threatening or irreversibly debilitating diseases. The program is designed to expedite the development and review of medical devices meeting Breakthrough criteria in the United States.

"We are thrilled to receive this Breakthrough designation as it will facilitate collaborative discussions with the FDA and help expedite the process of bringing a first-in-class migraine digital therapeutic to patients," said Austin Speier, Chief Strategy Officer of Click Therapeutics. "This is also powerful recognition of the innovative work led by our in-house science and development teams to create a new approach to treating migraine, one supported by early, promising clinical data."

"Breakthrough further affirms that our unique approach to unlock undruggable CNS targets has merit through the combination of digital neuroactivation and modulation (DiNaMo) and neurobehavioral interventions," said Shaheen Lakhan, MD, PhD, FAAN, Chief Medical Officer of Click Therapeutics. "Through this new paradigm, we aim to restore lives ravaged by debilitating brain diseases like migraine."

Additionally, The CT-132 program is validated by the active support of Click's Migraine Advisory Board comprising leading thought-leaders in headache research and clinical care chaired by Stewart Tepper, MD, professor of neurology of Geisel School of Medicine at Dartmouth and director of Dartmouth Headache Center.

Click has completed or initiated three clinical studies on CT-132, leveraging and expanding its proprietary Click Neurobehavioral Intervention (CNI) Platform in the process. When complete, the data from these trials will support the product's FDA regulatory submission.

About Click Therapeutics

Click Therapeutics, Inc. develops and commercializes software as prescription medical treatments for patients with unmet medical needs. Through cognitive and neurobehavioral mechanisms, Click's Digital Therapeutics™ enable change within individuals, and are designed to be used independently or in conjunction with biomedical treatments. The Clickometrics® adaptive data science platform continuously personalizes user experience to optimize engagement and outcomes. Following a groundbreaking clinical trial, Click's industry-leading smoking cessation program is available nationwide through a wide variety of payers, providers, and employers. Click's lead prescription program has entered a pivotal, fully remote, randomized, controlled trial on the Verily platform for the treatment of Major Depressive Disorder (MDD) in up to 360 adults. Click is progressing a broad pipeline of Digital Therapeutics™ across a variety of high-burden therapeutic areas, including MDD, Schizophrenia, Migraine, MS, Chronic Pain, Atopic Dermatitis, Acute Coronary Syndrome (ACS), Obesity, Oncology and more. For more information on Click, visit ClickTherapeutics.com.

References:

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