ABBOTT RECEIVES FDA'S BREAKTHROUGH DEVICE DESIGNATION TO EXPLORE USE OF DEEP BRAIN STIMULATION TO MANAGE SEVERE DEPRESSION

- Breakthrough Device Designations are given by the U.S. FDA to expedite the review of technologies that can improve the lives of people with life-threatening or debilitating conditions
- Each year, 2.8 million Americans will fail multiple depression therapies and be diagnosed with treatment-resistant depression (TRD)
- With Breakthrough Device Designation, Abbott's deep brain stimulation (DBS) System could become available as a new treatment option sooner for people affected by TRD

ABBOTT PARK, Ill., July 12, 2022 /PRNewswire/ -- Abbott (NYSE: ABT) today announced that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Device Designation to investigate the use of its deep brain stimulation (DBS) system in treatment-resistant depression (TRD), a form of major depressive disorder (MDD). Breakthrough Device Designation expedites the review of innovative technologies that can improve the lives of people with life-threatening or irreversibly debilitating diseases or conditions.

Abbott's DBS system is a personalized, adjustable therapy that involves implanting thin wires – or leads – into targeted areas of the brain. A pulse generator implanted under the skin in the chest is connected to the leads and produces electrical impulses that can modulate abnormal brain activity. While Abbott's DBS system has traditionally been used to help control symptoms for people with movement disorders, such as Parkinson's disease and essential tremor, evidence suggests that implanting electrodes in the part of the brain that regulates mood could help reduce symptoms of TRD. Abbott is working with the FDA to develop a plan for evaluating the device's safety and effectiveness for this purpose. One of the added benefits of certain Abbott DBS systems is that they can be used with NeuroSphere™ Virtual Clinic, a first-of-its-kind connected care technology that allows people to communicate with and receive care and therapy adjustments from their doctors remotely and from the comfort of their own home*.

For patients who suffer from TRD, a condition that costs the U.S. approximately $44 billion a year in healthcare, unemployment and lost productivity[1], deep brain stimulation has the potential to offer meaningful improvement of depressive symptoms. Currently, physicians have access to a range of treatments for MDD, also called clinical depression, including antidepressant medications and device therapies. Despite this, up to a third of individuals diagnosed with MDD – approximately 2.8 million Americans each year – do not respond even after trying four different antidepressant regimen approaches[1,2] resulting in TRD or difficult-to-treat depression. With each failed treatment, the chance of experiencing a decrease in symptoms drops. By the fourth failed treatment, as many as 83% of patients will relapse.[2]

To qualify for a Breakthrough Device Designation, a device technology must address an unmet need and show that it has the potential to provide for more effective treatment of life-threatening diseases or irreversibly debilitating conditions. The goal of the program is to provide patients and clinicians with timely access to these breakthrough treatments by accelerating their development, assessment and review while maintaining regulatory standards for pre-market approval. With Breakthrough Device Designation, Abbott's DBS system could become available as a new treatment option sooner for people affected by TRD.

"Breakthrough product development always requires bold thinking and collaboration, and Abbott is fully committed to the journey of providing people with new therapeutic options for their treatment-resistant depression," said Pedro Malha, vice president, neuromodulation, Abbott.

Abbott DBS therapy for treatment resistant depression is limited to investigational use only.

*Anywhere with a cellular or Wi-Fi connection and sufficiently charged patient controller.

About Abbott

Abbott is a global healthcare leader that helps people live more fully at all stages of life. Our portfolio of life-changing technologies spans the spectrum of healthcare, with leading businesses and products in diagnostics, medical devices, nutritionals and branded generic medicines. Our 113,000 colleagues serve people in more than 160 countries.

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[1] Zhdanava, M., Pilon, D., Ghelerter, I., Chow, W., Joshi, K., Lefebvre, P., & Sheehan, J. J. (2021). The Prevalence and National Burden of Treatment-Resistant Depression and Major Depressive Disorder in the United States. The Journal of clinical psychiatry, 82(2), 20m13699.

[2] Rush, A. J., Trivedi, M. H., Wisniewski, S. R., Nierenberg, A. A., Stewart, J. W., Warden, D., ... & Fava, M. (2006).

Acute and longer-term outcomes in depressed outpatients requiring one or several treatment steps: a STAR* D report. American Journal of Psychiatry, 163(11), 1905-1917.

SOURCE Abbott

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