

## **Otsuka and Click Therapeutics Initiate First-of-its-Kind Fully Remote Clinical Trial Using Digital Therapeutics as Adjunctive Therapy in Adults With Major Depressive Disorder**

- Primary objective of the Mirai study is to evaluate the effectiveness of digital therapeutics to reduce depressive symptoms in adults diagnosed with major depressive disorder (MDD) who are on antidepressant monotherapy
- Trial will run fully remotely utilizing the Verily Project Baseline platform, a first-of-its-kind trial design for MDD
- Otsuka is committed to exploring digital therapeutics in patients with serious mental illnesses like MDD, which affects more than 17 million adults in the US<sup>1</sup>

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PRINCETON, N.J. & NEW YORK--(BUSINESS WIRE)--Otsuka Pharmaceutical Development & Commercialization, Inc. (Otsuka) and Click Therapeutics, Inc. announce the initiation of the Mirai study, a landmark fully remote clinical trial to investigate the effectiveness of digital therapeutics in reducing depressive symptoms in adults diagnosed with major depressive disorder (MDD) who are on antidepressant monotherapy.

The pivotal, randomized, controlled trial will enroll up to 540 patients nationwide. Trial participation will be 10 weeks and efficacy will be evaluated as a change from baseline in the Montgomery-Åsberg Depression Rating Scale (MADRS) total score.

“This landmark clinical trial demonstrates Otsuka’s unwavering commitment to the evolution of clinically validated, FDA-cleared digital health solutions that support patients living with mental illnesses, like major depressive disorder,” said Kabir Nath, president and CEO, Otsuka North America Pharmaceutical Business Division, Otsuka America, Inc. “The COVID-19 pandemic has clearly demonstrated the need for digital treatments and fully remote e-clinical trials that go beyond the pill to empower patients, enhance connectivity between patients and their healthcare team, and ensure more diverse populations can participate in new clinical trials.”

According to the World Health Organization, depression is a leading cause of disability worldwide, and is a major contributor to the overall global burden of disease.<sup>2</sup> Click and Otsuka are committed to bridging the gaps between the global deficiency of mental health treatment access and the millions of patients in need of safe, effective, convenient and accessible care.

“While awareness of mental illness has grown steadily over the last decade, clinically validated therapeutic options available to patients and providers have remained essentially the same,” said David Benshoof Klein, CEO of Click Therapeutics. “Now more than ever, there is a need for a scalable digital solution that can dramatically expand access to mental health treatment without sacrificing the rigors of clinical validation or a patient-centered focus on engagement and user experience.”

Otsuka and Click will collaborate with Verily, a subsidiary of Alphabet, to execute the trial as a fully remote trial. The collaboration with Verily provides tools and technology to engage patients and clinicians, in order to increase the pace of studies and collect higher quality, more comprehensive data in a more naturalistic setting. The collaboration also enables the trial to proceed efficiently and safely in the face of the unique market challenges presented by COVID-19.

### **About the Otsuka and Click Therapeutic Collaboration**

Otsuka America, Inc., and Click Therapeutics, Inc., signed a collaboration agreement in 2019 to develop and commercialize prescription digital therapeutics for treatment of major depressive disorder (MDD), with the intent to address unmet medical needs among this patient population and to improve outcomes. Otsuka has committed to fully fund development of Click's novel mobile application for MDD, and to commercialize upon achievement of regulatory approvals.

### **About Otsuka**

Otsuka Pharmaceutical Co., Ltd. is a global healthcare company with the corporate philosophy: "Otsuka—people creating new products for better health worldwide." Otsuka researches, develops, manufactures, and markets innovative products, with a focus on pharmaceutical products to meet unmet medical needs and nutraceutical products for the maintenance of everyday health.

In pharmaceuticals, Otsuka is a leader in the challenging areas of mental, renal and cardiovascular health and has additional research programs in oncology and on several under-addressed diseases including tuberculosis, a significant global public health issue. These commitments illustrate how Otsuka is a "big venture" company at heart, applying a youthful spirit of creativity in everything it does.

Otsuka established a presence in the U.S. in 1973 and today its U.S. affiliates include Otsuka Pharmaceutical Development & Commercialization, Inc. (OPDC) and Otsuka America Pharmaceutical, Inc. (OAPI). These two companies' 1,700 employees in the U.S. develop and commercialize medicines in the areas of mental health, nephrology, and cardiology, using cutting-edge technology to address unmet healthcare needs.

OPDC and OAPI are indirect subsidiaries of Otsuka Pharmaceutical Company, Ltd., which is a subsidiary of Otsuka Holdings Co., Ltd. headquartered in Tokyo, Japan. The Otsuka group of companies employed 47,000 people worldwide and had consolidated sales of approximately USD 13.3 billion in 2020.

All Otsuka stories start by taking the road less traveled. Learn more about Otsuka in the U.S. at [www.otsuka-us.com](http://www.otsuka-us.com) and connect with us on LinkedIn and Twitter at @OtsukaUS. Otsuka Pharmaceutical Co., Ltd.'s global website is accessible at [www.otsuka.co.jp/en/](http://www.otsuka.co.jp/en/).

### **About Click**

Click Therapeutics, Inc. develops and commercializes software as prescription medical treatments for people 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 Clickmetrics® 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 is progressing a broad pipeline of Digital Therapeutics™ across a variety of high-burden therapeutic areas, including Major Depressive Disorder (MDD), Schizophrenia, Acute Coronary Syndrome (ACS), Chronic Pain, Insomnia, Chronic Obstructive Pulmonary Disease (COPD), Obesity, and more. For more information, visit [ClickTherapeutics.com](http://ClickTherapeutics.com).

### **Reference**

1. World Health Organization. Depression and Other Common Mental Disorders: Global Health Estimates. Geneva, Switzerland: World Health Organization. 2017.
2. World Health Organization. Newsroom, Fact Sheets, Depression. 30 January 2020 Available at: <https://www.who.int/news-room/fact-sheets/detail/depression>

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