



OTSUKA AND CLICK THERAPEUTICS COLLABORATE TO DEVELOP AND COMMERCIALIZE DIGITAL THERAPEUTICS FOR PATIENTS WITH MAJOR DEPRESSIVE DISORDER

Approach combines Otsuka's expertise in developing and commercializing treatments for mental health with Click's record of discovering and validating digital technologies as prescription medical treatments

SAN FRANCISCO, C.A. and NEW YORK, N.Y. – January 3, 2019 – Otsuka America, Inc., and Click Therapeutics, Inc., announce today that the companies have signed a collaboration agreement to develop and commercialize a prescription digital therapeutic for treatment of Major Depressive Disorder (MDD), with the intent to address unmet medical needs among this patient population and to improve outcomes.

This collaboration will leverage Click's demonstrated ability to discover and validate a software application and deploy it commercially, with Otsuka's expertise in developing approved prescription therapies for patients with serious mental illnesses, including Otsuka's established development and commercialization capabilities. The companies believe digital therapeutics align naturally with psychiatry and have significant potential to transform mental healthcare. Together, the companies aim to bring to market a new offering that will provide a novel treatment for patients with MDD.

Otsuka has agreed to commit capital to fully fund development of Click's novel mobile application 'CT-152' for MDD, and to commercialize this application world-wide upon achievement of regulatory approvals. Otsuka will pay Click up to \$10 million in upfront and regulatory milestone payments, along with an estimated \$20 million in development funding. An additional \$272 million in commercial milestone payments are contingent upon regulatory approvals. In addition, Click will receive tiered, double-digit royalties on global sales of the software and the digital therapeutic applications that result.

"This collaboration signals Otsuka's commitment to meet patients' unmet medical needs by developing solutions far beyond medication. Our goal is to deliver evidence-based cognitive therapies to a broader population of patients with MDD than is currently feasible, due to the challenges of a shortage of mental health professionals and limited time for them to conduct cognitive therapy," said Kabir Nath, president and CEO, Otsuka North America Pharmaceutical Business Division, Otsuka America, Inc. "We are proud to be one of the few pharmaceutical companies that continues to invest in developing medicinal and digital products for the treatment of mental illnesses, and we are doing so by breaking down barriers and collaborating with leading therapeutic technology companies, such as Click, which share our vision."

According to the World Health Organization, depression is the leading cause of disability worldwide, and is a major contributor to the overall global burden of disease.¹ Otsuka and Click believe that new approaches are needed to address this condition, including pioneering ways to use technology and data in support of better patient outcomes.

“Otsuka has established itself as the leading innovator in digital medicine for psychiatry, and we are thrilled to collaborate with their clinical and commercial experts on our CT-152 digital therapeutic for the treatment of depression. This collaboration symbolizes the growing recognition that digital therapeutics are a new category of treatment with the potential to become a routine treatment option for physicians for their patients,” said David Benschhof Klein, Chairman and CEO of Click. “The potential value of these treatments is clear: they provide validated tools that may be an effective treatment option to bring the power and accessibility of digital technologies for the benefit of the patient and physician. This recognition is also shared by regulators helping to build new pre-market review programs uniquely suited for digital therapeutics, while still retaining the traditional level of rigor and scrutiny that clinical studies require.”

About the prescription digital therapeutic for MDD and the agreement between Otsuka and Click:

- CT-152 is a software application (app) that will leverage evidence-based cognitive therapy principles and Click’s patient engagement platform to treat patients either independently or in conjunction with prescribed pharmacotherapies.
- The intent is that the app will be classified as Software as a Medical Device (SaMD) and will fall under the FDA regulatory framework that supports innovation and commercialization of digital tools while protecting patient health.

About Otsuka Pharmaceutical

Otsuka Pharmaceutical 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 for the treatment of diseases and nutraceutical products for the maintenance of everyday health.

In pharmaceuticals, Otsuka is a leader in the challenging area of mental health and has research programs 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 America, Inc. is a subsidiary of Otsuka Pharmaceutical Co., Ltd. headquartered in Tokyo, Japan. Both are part of Otsuka Holdings Co., Ltd. The Otsuka group of companies employed 46,000 people worldwide and had consolidated sales of approximately USD 11.1 billion in 2017.

All Otsuka stories start by taking the road less travelled. Learn more about Otsuka Pharmaceutical Company on its global website at <https://www.otsuka.co.jp/en>. Learn more about Otsuka in the U.S. at www.otsuka-us.com. Connect with us in the U.S. on Twitter at @OtsukaUS.

About Click Therapeutics

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 in the U.S through a wide variety of payers, providers, and employers. Click’s lead prescription program is entering into a multi-center, randomized, controlled, parallel-group, phase III FDA

registration trial for the treatment of Major Depressive Disorder in adults. For more information, visit ClickTherapeutics.com.

References:

1. World Health Organization. Depression Fact Sheet. Available at: www.who.int/news-room/fact-sheets/detail/depression

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