

Happify Health and Sanofi Sign Global Agreement to Bring Prescription Digital Mental Health Therapeutics to Individuals with Multiple Sclerosis
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NEW YORK, Sept. 17, 2019 /PRNewswire/ -- Happify Health, a global leader in mental health technology, today announced it signed an agreement with global biopharmaceutical company Sanofi (NASDAQ: SNY) to advance the application of digital therapeutics to address key co-morbidities for individuals living with multiple sclerosis (MS), including depression and anxiety.

Happify Health will develop a version of its digital platform specifically for people with MS and plans to submit the co-developed digital therapy to the U.S. Food and Drug Administration for clearance as a medical device.

"We've been preparing for our entry into prescription digital therapeutics for several years," said Ofer Leidner, co-founder and president of Happify Health. "Our experience as a successful direct-to-consumer application with nearly 4 million users and our commercial relationships with some of the nation's largest health plans and multinational employers, has allowed us to develop some highly differentiated capabilities. These capabilities, along with Sanofi's demonstrated commitment to digital transformation, made for an ideal collaboration rooted in exploring innovative, safe and effective therapies aiming to improve the lives of individuals with MS."

Once the MS-specific digital therapeutic has been developed through this joint collaboration, the road to FDA clearance will require new clinical validation to demonstrate the safety and efficacy of the therapy for people living with MS. Happify Health has already demonstrated effectiveness of its existing, non-specific solution in reducing anxiety and depression within the general population through a randomized controlled trial in 2018. Published in the *International Journal of Wellbeing*, the study found nearly a 25% reduction in symptoms of anxiety and more than a 25% reduction in symptoms of depression for those using Happify at the recommended level (a minimum of 16 activities completed over eight weeks). Additionally, research demonstrates industry-leading engagement rates for Happify Health users, with over 40% still active on the platform after 12 months.

A Market for Digital Therapeutics to Address MS and Mental Health

According to the National Multiple Sclerosis Society (NMSS), MS affects more than 2.3 million people worldwide, with 1 million being in the U.S.ⁱ Major depressive disorder is estimated to be as much as three times as prevalent in individuals with MS as in the general population; and anxiety is estimated to be 20 percent more prevalent in the MS population than in the general population.ⁱⁱ Up to half of all people living with MS show signs of depression.ⁱⁱⁱ

"We know that, for certain chronic conditions, mental health is perhaps the most significant underlying comorbidity," said Ameet Nathwani, Sanofi's chief medical officer and chief digital officer. "Happify Health's ability to address mental health issues so effectively in a digital environment provides an ideal complement to Sanofi's traditional therapies, allowing us to continue delivering on our commitment to bring innovative treatments and programs to people living with MS."

The use of digital therapeutics by pharmaceutical and life sciences companies continue to gain momentum, bolstered by growing validation of new digital modalities in enhancing traditional therapies, and as stand-alone treatments. PwC Health Research Institute (HRI) reports that more than 40% of pharmaceutical companies are developing digital therapeutics or connected devices, and another 42% are planning to do so within the next few years.^{iv} More than half of consumers surveyed by HRI reported they would use an FDA-approved digital therapeutic for treatment of a medical condition. Physicians are interested as well with 56% of surveyed physicians reporting that they have discussed an app or digital program with a patient in the last 12 months.^v

"Our differentiation is in providing a highly configurable platform that delivers proven, highly-engaging digital therapies for anxiety and depression, and enables users to take a greater role in managing aspects of their conditions," said Chris Wasden, Happify Health's Head of DTx. "Our platform provides a potential alternative or complement to current therapies, one which is safe, effective, and maximized for engagement, leading to greater treatment adherence and significant impact on an individual's quality of life."

Sanofi and Happify Health view this collaboration as the beginning of a long-term effort to use technology to improve outcomes in a cost-effective, accessible and patient-engaging way.

"Until now, physicians treating MS, have not had evidence-based, digital tools to treat comorbidities in tandem with the primary condition," said Bozidar Jovicevic, Sanofi's global head of digital medicine. "In collaboration with Happify Health, we now have the opportunity to develop an MS-specific digital therapeutic based on platform that is not only poised to affect outcomes, but is also proven to be engaging, a critical factor for improving overall patient health."

MTS Health Partners, L.P. served as a financial advisor to Happify Health on this transaction.

About Happify Health

Happify Health, a leader in mental health technology and digital therapeutics, breaks down barriers to achieving better mental health by creating an engaging, stigma-free environment that allows individuals to access digital interventions with any device – at the place and time when it matters most. Its evidence-based activities, combined with its digital, gamification approach, helps users build skills and change health behaviors to reduce symptoms of stress, anxiety and depression. Happify Health uses scientific research from positive psychology, CBT and mindfulness, and combines it with leading-edge technology to impact everyday lives. For more information go to www.happifyhealth.com.

About Sanofi

Sanofi is dedicated to supporting people through their health challenges. We are a global biopharmaceutical company focused on human health. We prevent illness with vaccines, provide innovative treatments to fight pain and ease suffering. We stand by the few who suffer from rare diseases and the millions with long-term chronic conditions. With more than 100,000 people in 100 countries, Sanofi is transforming scientific innovation into healthcare solutions around the globe.

ⁱ <https://www.nationalmssociety.org/About-the-Society/News/Landmark-Study-Estimates-Nearly%C2%A01-Million-in-the-U>

ⁱⁱ https://www.nationalmssociety.org/NationalMSSociety/media/MSNationalFiles/Brochures/Clinical_Bulletin_Emotional-Disorders-in-MS.pdf

ⁱⁱⁱ <https://my.clevelandclinic.org/health/transcripts/psychological-impact-of-multiple-sclerosis>

^{iv} <https://www.pwc.com/us/acceleration-by-regulation>

^v <https://www.pwc.com/us/en/industries/health-industries/top-health-industry-issues/digital-therapeutics-and-connected-care.html>

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SOURCE Happify Health

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