

Sumitomo Dainippon Pharma and BehaVR announce landmark deal for multiple virtual reality digital therapeutics

Development and commercialization plans include prescription digital therapeutics to treat social anxiety, generalized anxiety disorder, and major depressive disorder – with potential to impact millions worldwide.

October 18th, 2021 (Osaka, Japan & Nashville, TN) –Sumitomo Dainippon Pharma Co., Ltd. (Head Office: Osaka, Japan; Representative Director, President and CEO: Hiroshi Nomura; Securities Code: 4506, First Section of TSE) and BehaVR, Inc.,(Head Office: TN, U.S.) announce today that the companies have signed definitive agreements to develop and commercialize both prescription digital therapeutics and general wellness products for treatment of Social Anxiety Disorder (SAD), Generalized Anxiety Disorder (GAD), and Major Depressive Disorder (MDD) with the goal of bringing much needed tools to tackle the escalating global anxiety and depression crisis.

This collaboration combines BehaVR’s design and product development capabilities with Sumitomo Dainippon Pharma’s expertise in developing prescription therapeutics for patients with CNS-related disorders. It also leverages key strengths from each company’s go-to-market and commercial capabilities. The companies believe the unique neurological power of the virtual reality (VR) medium will transform access to care and power next generation delivery of anxiety and depression treatment for patients. The companies will pursue FDA clearance for three products that aim to alleviate the burden in patients with Social Anxiety, Generalized Anxiety or Major Depressive Disorder. Once FDA-cleared, they may be prescribed alongside other behavioral therapies and have the potential to be used in a variety of settings.

Sumitomo Dainippon Pharma has agreed to fund development of these novel VR therapies and to commercialize them globally upon achievement of each country’s regulatory approvals. Sumitomo Dainippon Pharma will pay BehaVR \$5 million in upfront payments and up to \$18 million in development milestone and R&D support payments, in addition to commercial and operational support fees. An additional up to \$140 million in milestone payments are contingent upon commercial success. In addition, BehaVR will receive tiered royalties on global sales of the digital therapeutic products that are delivered into market.

“This continued investment in our collaboration with BehaVR demonstrates Sumitomo Dainippon Pharma’s commitment to meet patients’ unmet behavioral health needs by developing digital therapies that go beyond pharmacological interventions. There is inadequate access to high quality mental health therapists in every country across the world. Our goal is to deliver high-impact digital VR therapies that are evidence-based to a broad global population of patients that continue to

struggle with SAD, GAD, and MDD,” said Hiroyuki Baba, Senior Executive Officer, Sumitomo Dainippon Pharma. “We are excited and proud to be pioneering the use of this fast-moving new medium of Virtual Reality to develop treatments for anxiety and depression related mental illnesses. I could not be more pleased with this extension to our important partnership with BehaVR, who share our vision of the impact that these new products will make.”

According to numerous reports by the National Institutes of Health, Center for Disease Control and the World Health Organization, anxiety levels are rising with over 19% of US adults suffering from an anxiety disorder and 5% of adults suffering from depression worldwide. The global COVID-19 pandemic has accelerated the issues. Both depression and anxiety are major contributors to the overall global burden of disease and rise of substance abuse. The treatment gap between the number of people with mental disorders and the number treated represents a major public health challenge. Sumitomo Dainippon Pharma and BehaVR believe that new approaches are needed to address these conditions, including commercializing the 20-year body of research that shows that the application of VR can be used in support of better patient outcomes.

“In my opinion, Sumitomo Dainippon Pharma is one of the most forward thinking and innovative pharmaceutical companies in the world today. We are thrilled to deepen our relationship to jointly increase our impact on health via clinically validated, FDA-cleared Virtual Reality-based digital therapies. Sumitomo Dainippon Pharma’s clinical and commercial expertise in this space will advance our joint objective of successfully scaling effective treatment options for anxiety and depression,” said Aaron Gani, Founder and CEO of BehaVR.

“Together we are innovating at the vanguard of digital therapeutics and early clinician, patient and consumer responses are extremely favorable. We believe this deep partnership between a global pharmaceutical company Sumitomo Dainippon Pharma and VR digital therapeutics leader is a significant advance for the field of Virtual Reality in healthcare, and for digital therapeutics broadly,” said Senator Bill Frist, MD, Founding Partner, BehaVR.

Understanding Virtual Reality Based Prescription Digital Therapeutics

Prescription Digital Therapeutics (PDTs) are clinically validated software-based interventions that prevent, manage, or treat a medical disease or disorder. PDTs are approved by regulators and available by prescription for use alone or alongside other medications or medical devices. BehaVR is creating VR PDTs informed by decades of neuroscience and cognitive research, along with evidence-based protocols that are translated into the medium to treat those with anxiety and depression. The intent of these three products, in this collaboration, is that they will be classified as a

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 the Collaboration between Sumitomo Dainippon Pharma and BehaVR

Sumitomo Dainippon Pharma's wholly-owned US subsidiary, Sunovion Pharmaceuticals Inc. and BehaVR, signed an initial collaboration agreement in June 2020 to co-develop a wellness product for those who suffer from stressful, fearful, and overwhelming feelings in a social setting. This initial collaboration was the foundation for this expanded relationship to develop and commercialize three prescription digital therapeutics for social anxiety, generalized anxiety and major depression upon achievement of regulatory approvals.

About Sumitomo Dainippon Pharma Co., Ltd.

Sumitomo Dainippon Pharma defines its corporate mission as "to broadly contribute to society through value creation based on innovative research and development activities for the betterment of healthcare and fuller lives of people worldwide." By channeling our efforts into the research and development of new drugs, Sumitomo Dainippon Pharma aims to realize its corporate mission and provides innovative and effective pharmaceutical solutions to people in Japan and globally. Sumitomo Dainippon Pharma's goal is to create innovative pharmaceutical products in the focus research areas with high unmet medical needs of Psychiatry & Neurology, Oncology, and Regenerative Medicine / Cell Therapy. In business fields other than pharmaceuticals, too, Sumitomo Dainippon Pharma is working on research and development and commercialization of innovative healthcare solutions under the framework of a frontier business, which goes beyond the traditional boundaries of a pharmaceutical company, with the aim of contributing to "wide-ranging well-being." Additional information about Sumitomo Dainippon Pharma is available through its corporate website at <https://www.ds-pharma.com>.

About BehaVR, Inc.

BehaVR is a new kind of digital therapeutics company dedicated to tackling the epidemic of anxiety-related challenges and disorders, to help curb chronic disease at scale, using the neurological power of VR. Partnering with the country's leading academic institutions, research institutes and pharmaceutical companies, we innovate at the intersection of behavioral science, virtual reality, and community design to develop immersive, evidence-based experiences that change peoples' lives.

At the core of our products is our stress, anxiety, and fear extinction (S.A.F.E.) protocol. S.A.F.E. builds a powerful foundation of short-term coping skills and long-term resiliency tools — giving people agency over their own health, and generating value, change, and better clinical outcomes for all stakeholders in the healthcare system.

The BehaVR Scientific Advisory Board includes leading researchers and authorities in the fields of behavioral neuroscience and medical virtual reality technology, including Amelia Aldao, PhD., Walter Greenleaf, Ph.D., Hunter Hoffman, Ph.D., Adriaan Louw, PT, Ph.D., and M. Zachary Rosenthal, PhD. For more information, visit www.behavr.com.

Media Contacts:

Sumitomo Dainippon Pharma Co., Ltd.

Corporate Communications

TEL: +81-6-6203-1407 (Osaka); +81-3-5159-3300 (Tokyo)

BehaVR

Rory Channer

rorychanner@behavr.com

703-989-0014

NOTE TO EDITORS: Demos, video and images are available upon request.

References

1. Anjel Vahratian, Stephen J. Blumberg, Emily P. Terlizzi,, and Jeannine S. Schiller. Symptoms of Anxiety or Depressive Disorder and Use of Mental Health Care Among Adults During the COVID-19 Pandemic, August 2020–February 2021. *MMWR Morb Mortal Wkly Rep.* 2021 Apr 2; 70(13): 490–494.
2. Evans-Lacko S, Aguilar-Gaxiola S, Al-Hamzawi A, et al. Socio-economic variations in the mental health treatment gap for people with anxiety, mood, and substance use disorders: results from the WHO World Mental Health (WMH) surveys. *Psychol Med.* 2018;48(9):1560-1571.
3. World Health Organization. Newsroom, Fact Sheets, Depression. 30 January 2020 Available at: <https://www.who.int/news-room/fact-sheets/detail/depression>
4. Maria A. Villarroel, Ph.D., and Emily P. Terlizzi, M.P.H. Symptoms of Depression Among Adults: United States, 2019. NCHS Data Brief No. 379, September 2020
5. NIH, Anxiety Disorders Fact Sheet; <https://www.nimh.nih.gov/health/statistics/any-anxiety-disorder>