



The McQuade Center for Strategic Research and Development Enters Collaboration Agreement with Rugen Holdings (Cayman) Limited to Develop Novel Treatment for Patients with Diverse Psychiatric Disorders

Activities will support the clinical development of Rugen's potential first-in-class, orally administered drug candidate with initial clinical focus on treatment-resistant depression.

PRINCETON, N.J. (October 30, 2020) – The McQuade Center for Strategic Research and Development, LLC (MSRD), a member of the global Otsuka family of pharmaceutical companies, announced today that it has entered an agreement with Rugen Holdings (Cayman) Limited, doing business as Rugen Therapeutics (Rugen), a pre-clinical biotechnology company focused on the development of novel treatments for central nervous system (CNS) disorders. The agreement will support the clinical development of therapeutics for patients living with a broad range of psychiatric disorders including treatment-resistant depression (TRD).

Under the terms of the agreement, MSRD and Rugen will collaborate to advance Rugen's orally administered drug candidate through Phase 1b clinical trials with the opportunity to expand the collaboration after those studies. The initial proof-of-concept studies focused on treatment for TRD.

Rugen's proprietary technology stems from its novel research into the circuit mechanisms of psychiatric disorders, facilitated by genetic-based animal models. This research has translated into its innovative drug candidate, which has potentially broad application across multiple psychiatric indications.

“Treatment-resistant depression is a major challenge for many patients who have yet to find success with antidepressants and other therapies,” said Robert McQuade, Ph.D., president, McQuade Center for Strategic Research and Development, LLC, and chief strategic officer, Otsuka Pharmaceutical Development & Commercialization, Inc. “Our collaboration with Rugen Therapeutics is part of our commitment to invest in breakthrough treatments that can potentially

change the way this condition is treated in the future. We are excited by early pre-clinical indicators of this therapy and look forward to exploring its potential.”

“Rugen applies the latest research on the genetic and biological basis of psychiatric disease to the development of novel therapies for diseases with high unmet need, like treatment resistant depression,” said Stacie Weninger, PhD., chair of Rugen’s Board of Directors. “We are thrilled to partner with MSRD to advance the clinical development of this potential first-in-class treatment. In addition, our work has implicated CSTC circuitry dysfunction in several additional neuropsychiatric conditions that could benefit from this therapeutic.”

About Rugen Therapeutics

Rugen Holdings (Cayman) Limited, dba Rugen Therapeutics is a biotech company discovering and developing novel, first-in-class, small-molecule drugs with the potential to address multiple psychiatric indications. Rugen's founders include Guoping Feng, Ph.D., Poitras Chair Professor, the Massachusetts Institute of Technology (MIT) and a member of the Broad Institute of MIT and Harvard University. Rugen was founded by the F-Prime Biomedical Research Initiative (FBRI), which seeks to advance the discovery of novel therapeutic agents for the treatment of neurological disorders by funding early-stage research in academia and the private sector.

About McQuade Center for Strategic Research and Development (MSRD)

Established in 2019 by the Otsuka pharmaceutical business in the U.S., the mission of MSRD is to search for, identify, and fund innovative early-stage research and development programs that have the potential to build the future portfolio of Otsuka products.

Otsuka is dedicated to investing in innovative and creative products in areas of unmet need and MSRD was created as an extension of this commitment to support and identify early stage opportunities that can change the landscape of treatments for mental illness and renal disorders. For more information, please visit <https://msrd-us.com/>.

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. Otsuka’s most recently approved product in the U.S. is the first-ever treatment for autosomal dominant polycystic kidney disease, a genetic disorder in which fluid-filled cysts develop in the kidneys over time, often leading to kidney failure.

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 billion in 2019.

All Otsuka stories start by taking the road less travelled. Learn more about Otsuka in the U.S. at 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/.

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