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Offering delicious products
for the sound mind and body

June 28, 2021

Company:	DyDo Group Holdings, Inc.
Representative:	Tomiya Takamatsu, President
	(Code 2590 on the First Section of the Tokyo Stock Exchange)
Inquiries:	Naokazu Hasegawa, Corporate Officer
	and General Manager of Corporate Communication Department

Notice of a Consolidated Subsidiary's Entry into a Licensing Agreement

DyDo Pharma, Inc., a consolidated subsidiary of DyDo Group Holdings, has entered, effective today, into a licensing and supply agreement with Catalyst Pharmaceuticals, Inc., for the development and commercialization of amifampridine that is expected to prove to be effective in treating Lambert-Eaton myasthenic syndrome ("LEMS") in Japan. Please see the separate press release for more information about the agreement.

Having identified the healthcare market, including the rapidly-growing life science field, as its next growth domain, the DyDo Group established DyDo Pharma in January 2019 in an effort to focus on pharmaceuticals for treating rare diseases (diseases which affect 50,000 or fewer patients in Japan). Such diseases, for which there are as yet no effective treatment options, have become a social issue. We work to secure a promising products pipeline in an effort to develop pharmaceutical drugs for rare congenital diseases and ultra-rare diseases, which have even fewer patients, in order to address this issue, and has signed the first license agreement as DyDo Pharma in January.

As the effect of this licensing and supply agreement on consolidated performance during the fiscal year ending January 2022 has already been incorporated into the full-year performance outlook that was announced on March 4, 2021, that outlook remains unchanged.

June 28, 2021

DyDo Pharma, Inc.

Notice of a Licensing Agreement for a Pharmaceutical for Treating Lambert-Eaton Myasthenic Syndrome

DyDo Pharma, Inc., (Head Office: Kita-ku, Osaka; president and representative director: Yasunori Inaoka) has entered, effective today, into a licensing and supply agreement covering Japanese market with Catalyst Pharmaceuticals, Inc., for the development and commercialization of amifampridine that is expected to prove to be effective in treating Lambert-Eaton myasthenic syndrome ("LEMS").

Amifampridine has already been approved for use in the treatment of LEMS in Europe, the U.S. and Canada. Catalyst, which markets and sells amifampridine tablets in the U.S. under the Firdapse® brand name.

With this agreement, DyDo Pharma acquires from Catalyst joint exclusive development and selling rights as well as exclusive commercialization rights to amifampridine in Japan where DyDo Pharma will develop and commercialize the product.

"DyDo Pharma's experienced team and commitment to rare diseases makes the company an attractive strategic development and distribution partner for Catalyst and for our amifampridine product Firdapse® for the treatment of LEMS," said Patrick J. McEnany, Chairman and CEO of Catalyst. "Given the limited availability of treatment options for LEMS in Japan, we look forward to working with DyDo Pharma to address this unmet medical need by hopefully providing a new treatment option for patients and their families."

"We are very pleased to have acquired a license for the Japanese rights for Firdapse®, which Catalyst sells in the U.S.," said Yasunori Inaoka, president and representative director of DyDo Pharma. "Going forward, we will pursue development with the goal of obtaining marketing authorization approval for Firdapse® as a treatment for LEMS in Japan so that we can offer a new therapeutic option to Japanese LEMS patients, who with their families are currently suffering in the absence of an approved treatment."

(Reference)

Lambert-Eaton myasthenic syndrome

Lambert-Eaton myasthenic syndrome is an autoimmune neuromuscular disorder in which a reduction in acetylcholine release from nerve terminals results in proximal muscle weakness, autonomic nervous symptoms, and other symptoms. It is one of a number of paraneoplastic neurological syndromes that accompany malignant tumors or precede tumors.

Catalyst pharmaceuticals

Catalyst Pharmaceuticals is a commercial-stage, patient-centric biopharmaceutical company focused on in-licensing, developing and commercializing novel high-quality medicines for patients living with rare diseases. With exceptional patient focus, Catalyst is committed to developing a robust pipeline of cutting-edge, first- or best-in-class medicines for other rare diseases. Catalyst's New Drug Application for Firdapse® (amifampridine) 10 mg tablets for the treatment of adults with LEMS was approved in 2018 by the U.S. Food & Drug Administration ("FDA"), and Firdapse® is commercially available in the United States as a treatment for adults with LEMS. Further, Canada’s national healthcare regulatory agency, Health Canada, recently approved the use of Firdapse® (amifampridine) for the treatment of patients in Canada with LEMS.