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Offering delicious products
for the sound mind and body

December 6, 2021

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Representative:	Tomiya Takamatsu, President
	(Code 2590 on the First Section of the Tokyo Stock Exchange)
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Notice of Phase 3 Clinical Trial Initiation in Japan by Consolidated Subsidiary

DyDo Pharma, Inc., a consolidated subsidiary of DyDo Group Holdings, Inc. (“Dydo Group”), has initiated a Phase 3 clinical trial of amifampridine ("DYD-301") that is expected to be effective in treating the patients with Lambert Eaton myasthenic syndrome (“LEMS”) in Japan.

DYD-301 is the therapeutic agent for LEMS that DyDo Pharma licensed from Catalyst Pharmaceuticals, Inc. (“Catalyst”) the joint exclusive development, & exclusive commercialization rights to amifampridine in Japan, and conducting clinical development in Japan.

Amifampridine has already been approved for use in the treatment of LEMS in Europe, the U.S. and Canada. Catalyst has already been marketing amifampridine tablets in the U.S. under the brand name of Firdapse® since 2018.

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 (which are defined as the number of patients below 50,000 in Japan). Such diseases, for which there are as yet no effective treatment options, have become a social issue. We, Dydo Pharma, 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.

As the effect of initiation of this clinical trial on consolidated financial 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.

(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.

DYD-301 (amifampridine Tablets 10 mg)

DYD-301 is an oral, nonspecific, voltage-dependent, potassium (K+) channel blocker that causes depolarization of the presynaptic membrane and slows or inhibits repolarization. This action results in the opening of slow voltage-dependent calcium (Ca2+) channels, allowing for a subsequent influx of Ca2+. In turn, it induces the exocytosis of synaptic vesicles containing Acetylcholine (ACh) to release more ACh into the synaptic cleft, enhancing neuromuscular transmission and providing for improved muscle function. Amifampridine was granted orphan drug designation by the Ministry of Health, Labour and Welfare in Japan and has previously been approved for use in the United States, Europe, and Canada for the treatment of adults with LEMS.

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 November, 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.

Licensing Agreement between Catalyst and DyDo Pharma

Please see the press release issued on June 28, 2021 for more information about the agreement.

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