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for sound mind and body

December 18, 2023

Company:	DyDo Group Holdings, Inc.
Representative:	Tomiya Takamatsu, President
	(Code 2590 on the Tokyo Stock Exchange Prime Market)
Inquiries:	Makiko Mihara, General Manager of Corporate Communication Department

Notice of a Consolidated Subsidiary's Submission of New Drug Application

DyDo Pharma, Inc. (DyDo Pharma), a consolidated subsidiary of DyDo Group Holdings, Inc. (Head Office: Kita-ku, Osaka; President: Tomiya Takamatsu), announces that DyDo Pharma has submitted today a new drug application of a drug (DYD-301, generic name: amifampridine phosphate) for the treatment of Lambert-Eaton myasthenic syndrome (LEMS) to Pharmaceuticals and Medical Devices Agency (PMDA). Please see the attached press release for more information.

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 are working 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.

The impact of this application for approval on the consolidated performance during the fiscal year ending January 2022 has already been incorporated into the full-year performance outlook that was announced on November 27, 2023, that outlook remains unchanged.

December18, 2023

DyDo Pharma, Inc.

Submission of new drug application of amifampridine phosphate (3,4-diaminopyridine) for Lambert-Eaton myasthenic syndrome (LEMS) in Japan

DyDo Pharma, Inc., (Head Office: Kita-ku, Osaka; president and representative director: Yasunori Inaoka) has submitted today a new drug application of a drug (DYD-301, generic name: amifampridine phosphate) for the treatment of Lambert-Eaton myasthenic syndrome (LEMS) to Pharmaceuticals and Medical Devices Agency (PMDA).

Amifampridine phosphate is a therapeutic agent for LEMS which DyDo Pharma has obtained from Catalyst Pharmaceuticals, Inc. (Catalyst) for the co-exclusive development, manufacturing and marketing license and the exclusive commercialization license for the treatment of LEMS in Japan, and then DyDo Pharma has been developing for LEMS patients in Japan.

Amifampridine phosphate is an ethical product which has already been approved for use in the treatment of LEMS in Europe, the U.S. and Canada. Catalyst has been marketing and selling amifampridine tablets in the U.S. under the brand name of Firdapse®.

(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 phosphate 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 phosphate was granted orphan drug designation by the Ministry of Health, Labour and Welfare in Japan and has previously been approved for use for adults and for children ages six to seventeen in the United States, and in Europe and Canada for the treatment of adults with LEMS.

Catalyst Pharmaceuticals

With exceptional patient focus, Catalyst is committed to developing and commercializing innovative first-in-class medicines that address rare neurological and epileptic diseases. Catalyst's flagship U.S. commercial product is FIRDAPSE® (amifampridine) Tablets 10 mg, approved for the treatment of Lambert-Eaton myasthenic syndrome ("LEMS") for adults and children ages six to seventeen. In January 2023, Catalyst acquired the U.S. commercial rights of FYCOMPA® (perampanel) CIII, a prescription medicine approved in people with epilepsy aged four and older alone or with other medicines to treat partial-onset seizures with or without secondarily generalized seizures, and with other medicines to treat primary generalized tonic-clonic seizures for people with epilepsy aged 12 and older. Further, Canada's national healthcare regulatory agency, Health Canada, has approved the use of FIRDAPSE for the treatment of adult patients in Canada with LEMS . On July 18, 2023, Catalyst acquired an exclusive license for North America for AGAMREE® (vamorolone) oral suspension 40 mg/mL, a novel corticosteroid treatment for Duchenne Muscular Dystrophy. AGAMREE previously received FDA Orphan Drug and Fast Track designations and was approved by the FDA for commercialization in the U.S. on October 26, 2023 with a launch planned for First Quarter 2024.

For more information about Catalyst Pharmaceuticals, Inc., visit the Company's website at www.catalystpharma.com. For Full Prescribing and Safety Information for FIRDAPSE®, visit www.firdapse.com. For Full Prescribing Information, including Boxed WARNING for FYCOMPA®, please visit www.fycompa.com. For Full Prescribing Information for AGAMREE, please visit https://www.agamree.com/

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