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DyDo Group Holdings

24. JULY 2023

Company:	DyDo Group Holdings, Inc.
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	(Code 2590 on the First Section of the Tokyo Stock Exchange)
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Results of a Phase 3 study of Amifampridine phosphate (3,4-diaminopyridine) for Lambert-Eaton myasthenia syndrome (LEMS) in Japan

DyDo Pharma, Inc. (DyDo Pharma), a consolidated subsidiary of DyDo Group Holdings, Inc. (Head Office: Kita-ku, Osaka; President: Tomiya Takamatsu) has obtained preliminary results of a favorable analysis (interim data at 6 months) in a Phase III clinical trial of DYD-301 (generic name: amifampridine phosphate) for the treatment of Lambert-Eaton myasthenia syndrome (LEMS) patients in Japan.

This study is a phase III clinical trial for adult LEMS patients treated by amifampridine phosphate for one year.

Based on the results of this study, DyDo Pharma is going to submit a new drug application (NDA) to PMDA and aim to acquire manufacturing and marketing approval in Japan.

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 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 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

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 U.S. commercial product portfolio consists of 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. For more information, please visit the Catalyst Pharmaceuticals website at https://catalystpharma.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