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Offering delicious products
for sound mind and body

September 24, 2024

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

Approval of New Drug Application (NDA) of Firdapse® Tablet 10mg Acquired by Consolidated Subsidiary

DyDo Group Holdings, Inc. (Head Office: Kita-ku, Osaka; President: Tomiya Takamatsu) announces that DyDo Pharma, Inc. (DyDo Pharma), a consolidated subsidiary of the Group, has obtained an approval of the NDA of Firdapse® Tablet 10mg (generic name: amifampridine phosphate, DYD-301) for the indication of improving muscle weakness in patients with Lambert-Eaton myasthenic syndrome (LEMS) in Japan. 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, to focus on pharmaceuticals for treating rare diseases (which consist of fewer than 50,000 patients in Japan). Such diseases, for which there are no effective treatment options, have become a social issue. We are working to secure a promising products pipeline with pharmaceutical drugs for rare congenital diseases and ultra-rare diseases, which have even fewer patients.

The impact of this approval on the consolidated performance during the fiscal year ending January 2025 has already been incorporated into the full-year performance forecasts that were announced on August 27, 2024, and that remain unchanged.

September 24, 2024

DyDo Pharma, Inc.

Firdapse® Tablet 10mg Approved for the Treatment of Muscle Weakness in Lambert-Eaton Myasthenic Syndrome in Japan

DyDo Pharma, Inc. (Headquarters: Kita-ku, Osaka; President and Representative Director: Yasunori Inaoka; hereinafter referred to as "DyDo Pharma") announced today that the Ministry of Health, Labor and Welfare of Japan has approved the NDA of Firdapse® Tablet 10mg (generic name: amifampridine phosphate) for the indication of improving muscle weakness in patients with Lambert-Eaton myasthenic syndrome ("LEMS") in Japan.

Firdapse® Tablet 10mg has been developed in Japan by DyDo Pharma after entering into an exclusive License and Supply Agreement with Catalyst Pharmaceuticals, Inc. ("Catalyst") Under the terms of the agreement, DyDo Pharma has an exclusive license to market and commercialize Firdapse for LEMS in Japan, and the parties have co-exclusive rights to develop the product in the country. The drug has already been approved for the treatment of LEMS in Europe, Canada and the United States and is marketed by Catalyst under the trade name Firdapse® in the United States.

Yasunori Inaoka, President and Representative Director, commented as follows:
"We are very pleased to receive the marketing authorization for Firdapse® Tablet 10mg in Japan today. We will make the process for launch as fast as possible to deliver this drug to LEMS patients in Japan who have no effective treatment for their disease."

【Summary of Approved Details】

Trade Name	Firdapse® Tablet 10mg
Generic Name	amifampridine phosphate
Indications	Improvement of muscle weakness in Lambert-Eaton myasthenic syndrome
Dosage & Administration	The usual adult dosage of amifampridine is an initial dose of 5 mg orally three times daily. Depending on the patient's condition, the dosage may be increased or decreased in the range of 5 to 30 mg orally three to five times a day, with dosage increases of 5 mg per day at intervals of at least three days. The daily dose should not exceed 100 mg.

(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.

Firdapse® Tablet 10mg

Firdapse® Tablet 10mg 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, Labor 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, Inc.

Catalyst (Nasdaq: CPRX) is a biopharmaceutical company committed to improving the lives of patients with rare diseases. With a proven track record of bringing life-changing treatments to the market, we focus on in-licensing, commercializing, and developing innovative therapies. Guided by our deep commitment to patient care, we prioritize accessibility, ensuring patients receive the care they need through a comprehensive suite of support services designed to provide seamless access and ongoing assistance. Catalyst maintains a well-established U.S. presence while actively seeking to expand its global commercial footprint through strategic partnerships. Catalyst is headquartered in Coral Gables, FL., and was recognized on the Forbes 2024 list as one of America's most successful small-cap companies.

For more information, please visit Catalyst's website at www.catalystpharma.com.

Licensing Agreement between Catalyst Pharmaceuticals, Inc. and DyDo Pharma, Inc.

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

The End