June 8, 2020

BSE Limited,
Department of Corporate Services,
P. J. Towers, Dalal Street,
Mumbai Samachar Marg,
MUMBAI - 400 001.

✔ **National Stock Exchange of India Ltd.,**
Exchange Plaza,
Bandra Kurla Complex,
Bandra (East),
MUMBAI - 400 051.

Dear Sir/Madam,

Sub: Disclosure pursuant to Regulation 30 of the SEBI (Listing Obligations and Disclosure Requirements) Regulations, 2015.

Enclosed is a Press Release as regards grant of Orphan Drug Designation by U.S. FDA to mexiletine hydrochloride for the treatment of myotonic disorders.

This may kindly be considered as a disclosure pursuant to Regulation 30 of the SEBI (Listing Obligations and Disclosure Requirements) Regulations, 2015.

For LUPIN LIMITED

RAJVARDHAN VISHNU SATAM

Digitally signed by RAJVARDHAN VISHNU SATAM
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Date: 2020.06.08 10:19:56 +05'30'

R. V. SATAM
COMPANY SECRETARY
(ACS - 11973)

Encl- : a/a.

Press Release

BSE: 500257	NSE: LUPIN	REUTERS: LUPIN.BO	BLOOMBERG: LPCIN

U.S. FDA Grants Mexiletine Orphan Drug Designation

Mumbai, India | Zug, Switzerland, June 08, 2020: Pharma major Lupin Limited (Lupin) is announced today that the US Food and Drug Administration (U.S. FDA) has granted Orphan Drug Designation (ODD) to mexiletine hydrochloride for the treatment of myotonic disorders.

Myotonic disorders are a group of heterogeneous, inherited, neuromuscular disorders characterized by a shared symptom called myotonia. Myotonia is an inability to relax a contraction of skeletal muscle which originates from a voluntary muscular contraction such as shaking someone's hand and blinking, or everyday activities such as walking across a street and climbing stairs. Mexiletine reduces myotonia symptoms, resulting in a significant improvement in patient quality-of-life and other functional outcomes[1].

The FDA grants ODD status to medicines intended for the treatment, diagnosis or prevention of rare diseases or disorders that affect fewer than 200,000 people in the US.

Vinita Gupta, CEO, Lupin Limited said, "There is a serious unmet medical need for the management of symptoms in patients with myotonic disorders. The decision by the U.S. FDA to grant orphan drug designation to mexiletine brings us closer to providing a licensed treatment option for patients in the U.S., and we are pleased to have this opportunity to further our commitment to these patients."

Notes:

Myotonic Disorders and Non-Dystrophic Myotonic (NDM) Disorders

Myotonic disorders are a group of heterogeneous, inherited, neuromuscular disorders characterized by a shared symptom called myotonia. Myotonia is described as an inability to relax a contraction of skeletal muscle which originates from a voluntary muscular contraction such as shaking someone's hand and blinking, or everyday activities such as walking across a street and climbing stairs. Taken together, these myotonic disorders are rare and comprise two groups: the myotonic dystrophies and the non-dystrophic myotonic disorders[3].

Myotonic dystrophy (DM) affects multiple systems in the body. The two types of DM (DM1 and DM2) differ in prevalence, affected genes, disease progression, symptoms and severity of symptoms, with sub classifications based on disease onset, making it difficult to know how the disorder will affect patients. DM1 is the most common form, with the global consensus that myotonic dystrophies, based upon estimates from the NIH and others for western European and North American populations, affect 12.5 per 100,000 individuals[4,5].

Non-dystrophic myotonias (NDM) are caused by mutations within ion channels in the sarcolemma membrane of skeletal muscles and affects 1 in 100,000 people[2]. Non-dystrophic myotonias exhibit both sodium and chloride channelopathies which result in altered membrane excitability. Unlike DM, for patients with NDM myotonia is the most prominent symptom and demonstrates different phenotypes in subgroups of NDM disorders, and can affect different parts of the body, such as legs, arms or facial muscles, more severely.

Myotonia in NDM patients has an onset in childhood and persists across their lifetime. Patients perceive that myotonia increases in severity over time, impacting daily life. Myotonia is described by patients in a variety of ways (stiffness, cramps, pain, difficulty releasing a fist, or difficulty swallowing or eating) which can contribute to substantial delays in diagnosis and treatment, leading to decreased patient quality-of-life and often significant disability.

Mexiletine

In randomized controlled trials in adult patients with non-dystrophic myotonia, mexiletine (167 to 500 mg/day) has been shown to significantly reduce myotonia compared to placebo, reducing skeletal muscle hyperexcitability through its use-dependent, voltage-gated, sodium channel blocking actions which are independent of the cause of channel function. This resulted in an improvement in patient quality-of-life and other functional outcomes, with gastro-intestinal discomfort reported as the most common adverse event, demonstrating mexiletine to be safe and well tolerated in this patient population[1,5].

About Lupin

Lupin is an innovation-led transnational pharmaceutical company headquartered in Mumbai, India. The Company develops and commercializes a wide range of branded and generic formulations, biotechnology products and APIs in over 100 markets in the U.S., India, South Africa and across Asia Pacific (APAC), Latin America (LATAM), Europe and Middle-East regions.

The Company enjoys leadership position in the cardiovascular, anti-diabetic, and respiratory segments and has significant presence in the anti-infective, gastro-intestinal (GI), central nervous system (CNS) and women's health areas. Lupin is the third largest pharmaceutical company in the U.S. by prescriptions and in India by global revenues. The Company invests 9.6 % of its revenues on research and development.

Lupin has fifteen manufacturing sites, seven research centres, more than 20,000 professionals working globally, and has been consistently recognized as a 'Great Place to Work' in the Biotechnology & Pharmaceuticals sector.

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Facebook: www.facebook.com/LupinWorld/

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*Safe Harbor Statement

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2. Emery AE et al. Neuromuscular Disorders 1991
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