



June 3, 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 the Company entering into distribution agreement with three companies for its orphan drug NaMuscla[®] (mexiletine). Exeltis Healthcare S.L, Cresco Pharma B.V and Macure Pharma ApS will commercialize NaMuscla[®] for the symptomatic treatment of myotonia in adults with non-dystrophic myotonic disorders in certain EU territories. NaMuscula[®] is the first and only licensed product for this indication.

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

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

Encl- : a/a.

Lupin Signs Distribution Agreement in Key EU Territories for Orphan Drug NaMuscla®

Enables expanded patient access of rare disease medicine to treat myotonia symptoms in non-dystrophic myotonic disorders in three key territories

Mumbai, India | Zug, Switzerland, June 03, 2020: Pharma major Lupin Limited (Lupin) is pleased to announce that it has entered into distribution agreement with three companies for its orphan drug NaMuscla® (mexiletine). Exeltis Healthcare S.L, Cresco Pharma B.V and Macure Pharma ApS will commercialize NaMuscla® for the symptomatic treatment of myotonia in adults with non-dystrophic myotonic (NDM) disorders in certain EU territories. NaMuscla® is the first and only licensed product for this indication.

NDM disorders are a group of rare, inherited neuromuscular disorders which cause the inability to relax muscles following voluntary contraction. NaMuscla® reduces myotonia symptoms in adult patients, resulting in a significant improvement in patient quality-of-life and other functional and clinical outcomes¹. NaMuscla®, which has been designated orphan drug status, received EU marketing authorization in December 2018.

Under the agreements announced today, Exeltis Healthcare S.L will commercialize NaMuscla® in Spain and Portugal, Cresco Pharma B.V will commercialize NaMuscla® in the Netherlands and Macure Pharma ApS in the Nordic countries. Lupin will continue commercialization of NaMuscla® in Germany and UK and will launch the product in Austria and France later this year.

“These distribution agreements represent an important milestone for Lupin as we roll out commercialization of NaMuscla® across Europe. Collaborating with partners that are highly effective in their focus territories ensures patients will receive the drug in as effective manner as possible,” said **Thierry Volle, President EMEA, Lupin**. “Lupin is committed to addressing the unmet needs of patients with NDM through the establishment of country-specific solutions and to ensuring patient access across Europe in alignment with national health authorities, healthcare providers and patient advocacy groups.”

Today, more than 7,500 people in Europe^{2,3,4} living with NDM have limited access to a licensed treatment for myotonia that can reduce the daily burden of this disabling, lifelong symptom. Limited access leads to inconsistent medication supply, administrative challenges and associated financial burdens, which, along with low awareness and limited clinical experience among healthcare professionals due to rare nature of disease, may result in significant harm to patients⁵. Lupin recently obtained approvals to begin a paediatric trial as part of the paediatric investigation plan for NaMuscla® and a post authorization [safety] study to address long-term safety and treatment efficaciousness on patient reported outcomes. Both trials will begin later this year.

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 can be 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.

Non-dystrophic myotonias (NDM) are a sub-set of rare (prevalence of 1:100,000⁴), inherited, myotonic disorders which are caused by mutations within ion channels in the sarcolemma membrane of skeletal muscles. Non-dystrophic myotonias exhibit both sodium and chloride channelopathies which result in altered membrane excitability. 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.

NaMuscla[®] (mexiletine)

NaMuscla[®] is the first and only antimyotonic agent licensed to treat symptomatic myotonia in adults with non-dystrophic myotonic disorders across Europe. In randomized controlled trials, NaMuscla[®] (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 NaMuscla[®] to be safe and well tolerated¹.

Lupin Limited

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.

Please visit www.lupin.com for more information.

Follow us on Twitter: www.twitter.com/LupinGlobal | LinkedIn: www.linkedin.com/company/lupin/

Facebook: www.facebook.com/LupinWorld/

Exeltis Healthcare S.L

Exeltis is a fast-growing division of the integrated health sciences group Insud Pharma. With a global footprint spanning over 40 countries, Exeltis has a team of more than 4,000 professionals supported by a global manufacturing network. It boasts a leadership position in the Women's Health segment, and in recent years, Exeltis has also diversified into Central Nervous System (CNS), Ophthalmology and Endocrinology. Exeltis is constantly innovating and seeking new treatments and devices to improve patients health and wellbeing around the world.

Cresco Pharma B.V

Cresco Pharma B.V. is a privately owned Dutch pharmaceutical company founded in 2008. The company is headquartered in Meerssen, the Netherlands. Cresco commercializes a range of products for the treatment of severe chronic patients. The company is focusing on the commercialization of respiratory products and neurology products. The mission is to improve care for patients by the distribution of best in class products and services. The company is key player in distributing combinations of inhaled antibiotics with fast nebulizer systems to contribute to improved patient adherence. Also in the treatment of advanced Parkinson's disease, the company recently introduced a next generation of drug and pump therapy. Cresco Pharma is managed by an experience board of directors and has small dedicated team with focused on caregivers in hospitals.

Macure Pharma ApS

Macure Pharma is a rapidly growing, Nordic specialty company focused on niche pharmaceuticals. The company's head office is in Copenhagen, Denmark. Macure Pharma has a full presence in each of the Nordic countries (Denmark, Norway, Finland & Sweden) with separate warehousing, distribution & sales force in each market.

For further information or queries please contact –

| | |
|--|---|
| Arvind Bothra Head – Investor Relations and Corporate Communications Email: arvindbothra@lupin.com Tel: +91 22 6640 8237 | Manjira Sharma General Manager – Corporate Communications Email: manjirasharma@lupin.com Tel: +91 22 6640 2532 |
|--|---|

[*Safe Harbor Statement](#)

References:-

1. NaMuscla Summary of Product Characteristics, Assistance Publique – Hopitaux de Paris (AP-HP) sponsor of MYOMEX
2. Trivedi et al. 2013
3. Eurostat
4. Emery AE et al. Neuromuscular Disorders 1991
5. M Schey C et al., Non-dystrophic myotonic disorders: Patients' Insights on Treatment Access – poster presented at the 9th World Congress on Rare Disease and Orphan Drugs. June 19-18, 2019. Berlin, Germany;