January 9, 2023

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

National Stock Exchange of India Limited
Exchange Plaza,
Bandra Kurla Complex,
Bandra (East),
Mumbai - 400 051.

Dear Sir/Madam,

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

We are pleased to enclose a Press Release as regards, receipt of approval from the Spanish Ministry of Health for the reimbursement of Company's NaMuscla® (mexiletine) for the symptomatic treatment of myotonia in adults with non-dystrophic myotonic disorders.

This may kindly be considered as a disclosure pursuant to Regulation 30 of the Listing Regulations.

The above is for your information and dissemination.

Thanking you,

For LUPIN LIMITED

Rajvardhan Vishnu Satam

Digitally signed by Rajvardhan Vishnu Satam
DN: c=IN, st=Maharashtra, 2.5.4.20=c19d8ef961d9fa59e973a093a4d3924b2532eb2f496ea7e2abcf74700f5375b7, postalCode=400104, street=2404,SEJAL TOWER,SEJAL PARK,LINK ROAD,GOREGAON WEST,Mumbai,Motilal Nagar,Borivali,Mumbai Suburban, pseudonym=9a4b7cd219ea516ad56e6d651dcbbe5b, title=0191, serialNumber=df8ebe60a88c796663c738ea25bfa0b475d1959726cdb67a2ff09c4242771b2a, o=Personal, cn=Rajvardhan Vishnu Satam
Date: 2023.01.09 16:13:42 +05'30'

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

Encl: a/a

Press Release

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

Lupin and Exeltis Announce Reimbursement Approval of NaMuscla® in Spain for the Symptomatic Treatment of Myotonia in Adults with non-dystrophic myotonic (NDM) Disorders

Agreement enables sustainable patient access of the only EU-approved treatment for myotonia symptoms in non-dystrophic myotonic disorders

Mumbai, Zug, January 09, 2023: Global pharma major Lupin Limited (Lupin) and Exeltis Healthcare S.L (Exeltis) announced today that the Spanish Ministry of Health (MSCBC) has approved the reimbursement of Lupin's NaMuscla® (mexiletine) for the symptomatic treatment of myotonia in adults with non-dystrophic myotonic (NDM) disorders on the National Health and Pharmacy Service. NaMuscla® is the first and only licensed product for this indication in Europe and will be commercialized by Lupin's partner Exeltis in Spain.

NDM disorders are a group of rare, inherited neuromuscular disorders with an estimated prevalence of 1 case per 100,000 inhabitants in Spain[1], and is characterized by the inability to relax muscles following voluntary contraction (myotonia). NaMuscla® reduces myotonia symptoms in people with NDM, resulting in a significant improvement in quality of life and other functional and clinical outcomes for patients[2]. NaMuscla®, which has been designated orphan drug status, received EU marketing authorization in December 2018[3].

"NDM patients in Spain will now be able to access NaMuscla® in a sustainable way. We are grateful to all stakeholders involved in the approval process, especially our partner Exeltis," said **Thierry Volle, President EMEA, Lupin**. "Lupin's transformational journey into specialty disease areas continues, with future investments planned for neuromuscular diseases, to meet the unmet needs of patients."

"We are excited by this decision which will enable us to provide a new, innovative treatment option that addresses the unmet needs of patients with NDM as soon as possible," said **Alberto Fábregas Gil, Director General Spain and Portugal, Exeltis**. "This news allows us to distribute NaMuscla® quickly and effectively and strengthen our position in the central nervous system area."

To date, people in Spain living with NDM have had limited access to a licensed treatment for myotonia that can reduce the daily burden of this disabling, lifelong condition. Limited access leads to inconsistent medication supply, administrative challenges, and associated financial burdens. This, alongside limited clinical experience among healthcare professionals due to the rare nature of the disease, may result in significant harm to patients.

Lupin's pediatric trial (NCT04624750), part of the pediatric investigation plan for NaMuscla® in children with myotonic disorders, is ongoing and successfully concluded patient enrolment in a first

patient cohort group who were offered and rolled over into a 2-year follow-up study (NCT04622553). A post-authorization study to address long-term safety and treatment effects of NaMuscla® on patient-reported outcomes in adults with NDM (NCT04616807) has concluded patient enrollment and will provide 3 years prospective data on NaMuscla® in a real-life setting.

Notes for Editors

About Myotonic Disorders and Non-Dystrophic Myotonias (NDM)

Myotonic disorders are a group of heterogeneous, inherited, neuromuscular disorders characterized by a shared symptom called myotonia[4]. 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[4].

Non-dystrophic myotonias (NDM) are a sub-set of rare (prevalence of 1:100,000[1]), 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[5]. 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[5].

Myotonia in patients with NDM 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[4, 6].

About NaMuscla® (mexiletine)

NaMuscla® is the first and only antimyotonic agent licensed to treat symptomatic myotonia in adults with non-dystrophic myotonic disorders in Europe[7]. 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 tolerated[2, 3, 7].

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 the Asia Pacific (APAC), Latin America (LATAM), Europe, and Middle East regions.

The Company enjoys a leadership position in the cardiovascular, anti-diabetic, and respiratory segments and has a 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. The company invested 8.7% of its revenue in research and development in FY22.

Lupin has 15 manufacturing sites, 7 research centers, 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: https://twitter.com/LupinGlobal|LinkedIn: https://www.linkedin.com/company/lupin
Facebook: http://www.facebook.com/LupinWorld/

Contact for media inquiries:

Consilium Strategic Communications
lupin@consilium-comms.com

Shweta Munjal
Vice President & Global Head – Corporate Communications
shwetamunjal@lupin.com

About Exeltis

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) and other therapeutic areas.

References:

1. Emery AEH, Neuromuscular Discord 1991;1:19-29
2. Vicart S, et al. Neuromuscular Discord 2021;31:1124-1135
3. NaMuscla®. Summary of Product Characteristics. EU/1/18/1325/001-004. 18 December 2018
4. Stunnenberg, et al. Muscle Nerve 2020;62(4):430-444
5. Matthews E, et al. Brain 2010;133:9–22
6. Trivedi JR, et al. Brain 2013;136:2189-200
7. Matthews E, et al. Pract Neurol 2021;0:1–10

Job Code: EU-NAM-2301-00001