



February 9, 2022

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 the SEBI (Listing Obligations and Disclosure Requirements) Regulations, 2015.

Enclosed is a Press Release as regards the Company having entered into a distribution agreement with Medis for its orphan drug NaMuscla® (mexiletine). Medis will commercialize NaMuscla® for the symptomatic treatment of myotonia in adults with non-dystrophic myotonic (NDM) disorders in Central and Eastern European countries.

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

Thanking you,

Yours faithfully,
For LUPIN LIMITED

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



Encl: a/a.

LUPIN LIMITED

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Lupin Signs Distribution Agreement with Medis for Orphan Drug NaMuscla®

Agreement enables expanded patient access of the only EU-approved treatment for myotonia symptoms in non-dystrophic myotonic disorders in Central and Eastern European territories

Mumbai, Zug, February 09, 2022: Global pharma major, Lupin Limited (Lupin) announced today that it has entered into a distribution agreement with Medis for Lupin's orphan drug NaMuscla® (mexiletine). Medis will commercialize NaMuscla® for the symptomatic treatment of myotonia in adults with non-dystrophic myotonic (NDM) disorders in Central and Eastern European countries. NaMuscla® is the first and only licensed product for this indication.

NDM disorders are a group of rare, inherited neuromuscular disorders which is characterized by the inability to relax muscles following voluntary contraction. NaMuscla® reduces myotonia symptoms in people with NDM, resulting in a significant improvement in quality of life and other functional and clinical outcomes for patients¹. NaMuscla®, which has been designated orphan drug status, received EU marketing authorization in December 2018².

Under the agreement announced today, Medis will initially focus on the commercialization of NaMuscla® in the Central and East European countries, namely Croatia, Czech Republic, Hungary, Slovakia, and Slovenia in the first phase. Lupin will continue commercialization of NaMuscla® in Germany, France, and the UK.

"The distribution agreement represents an important milestone for Lupin as we continue the roll out of NaMuscla® across Europe. We know that collaborating with partners which are highly focused in their territories means patients receive medicines in the most efficient way," said **Thierry Volle**, **President EMEA, Lupin**.

"At Medis, we are very excited to partner with Lupin and are further committed to using our expertise in comprehensive commercialisation to provide new, innovative treatment options like NaMuscla® that address patients' unmet needs. For us, each patient counts," said **Martina Perharič**, **CEO of Medis**. "As a pioneer in full-service pharmaceutical distribution for the CEE region, we have gained extensive knowledge of the complex markets in the region. This allows us to launch NaMuscla® quickly and effectively in selected countries and provide excellent support to our partner Lupin."

Today, around 1,000 people in Central and Eastern Europe living with NDM have limited access to a licensed treatment for myotonia that can reduce the daily burden of this disabling, lifelong symptom³⁻⁵. Limited access leads to inconsistent medication supply, administrative challenges, and associated financial burdens. Coupled with low awareness and limited clinical experience among healthcare professionals due to the rare nature of the disease, may result in significant harm to patients⁴.

Lupin has recruited the first study participants in a pediatric trial as part of the pediatric investigation plan for NaMuscla® in children (NCT04624750) and a post-authorization study to address long-term safety and treatment effects on patient-reported outcomes in adults (NCT04616807).

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. 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 1:100,000³), 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 excitability⁶. 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 severely⁶.

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^{4,7}.

About NaMuscla® (mexiletine)

NaMuscla® is the first and only antimyotonic agent licensed to treat symptomatic myotonia in adults with non-dystrophic myotonic disorders in Europe⁸. 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^{1,2,8}.

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 the 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



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women's health areas. Lupin is the third-largest pharmaceutical company in the U.S. by prescriptions. The company invested 9.6% of its revenue in research and development in FY21.

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/>

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About Medis d.o.o.

With over 30 years of experience, Medis is recognized as a commercialization partner of choice for the global pharmaceutical and biotechnology companies entering the CEE region. By leveraging the marketing know-how, scientific expertise, and product knowledge Medis strives to make advanced medical treatments accessible to every patient in this region. Medis operates fully owned subsidiaries in 17 countries and provides its partners with a whole range of services. For more information about Medis, please visit <http://www.medis.com> or [LinkedIn](#).

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