Press Release

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

Lupin Announces Launch of Orphan Drug NaMuscla® in Germany and the UK for the Treatment of Myotonia in Non-Dystrophic Myotonic Disorders

Zug, Mumbai, February 1, 2019: Lupin is pleased to announce that NaMuscla® (mexiletine) has been launched in Germany and the United Kingdom (UK). NaMuscla® is approved across the European Union (EU) for the symptomatic treatment of myotonia in adults with non-dystrophic myotonic (NDM) disorders. These disorders are a group of rare, inherited neuromuscular conditions in which myotonia, the inability to relax muscles following voluntary contraction, is the most prominent clinical symptom. NaMuscla® reduces myotonia symptoms in adult patients, resulting in a significant improvement in patient quality-of-life and other functional outcomes[1,5].

The launch of NaMuscla® in Germany and the UK follows the European Commission's approval of the product on 18 December 2018. NaMuscla®, designated an Orphan Drug by the European Medicines Agency (EMA), is the first treatment to be licensed across the EU for the symptomatic treatment of myotonia in adults with NDM disorders. The product will be commercialized in Germany by Hormosan Pharma GmbH, a full subsidiary of Lupin Ltd., and in the UK by Lupin Healthcare (UK) Ltd.

"We are delighted to be able to provide patient and market access to NaMuscla® in Germany and the UK," **said Thierry Volle, President EMEA, Lupin.** "NaMuscla® is the first licensed therapy for myotonia across the EU and offers an effective treatment option for patients living with this life-altering symptom. We look forward to additional launches for patients in other EU territories through 2019 and 2020."

Lupin has ongoing partnering discussions for the commercialization of NaMuscla® in European territories outside of Germany and the UK.

Prior to the approval of NaMuscla®, the vast majority of more than 7500 people in Europe[2,3,4] living with NDM had limited access to a licensed treatment for myotonia which reduced the daily burden of this life-altering symptom. Limited access leads to inconsistent medication supply, administrative challenges to both treating physicians and patients and associated financial burdens; this, along with low awareness and clinical experience among healthcare professionals, can result in harm to patients[4]. The EMA recognized the importance of having an effective therapy in adult NDM patients throughout the EU by granting NaMuscla® Orphan Drug status and the corresponding market exclusivity protection.

About 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.

Press Release

Non-dystrophic myotonias (NDM) are a sub-set of rare (prevalence of 1:100,000[6]), 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 over the patient's lifetime – significantly impacting the patient's 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.

About NaMuscla® (mexiletine)

NaMuscla® is an antimyotonic agent licensed to treat symptomatic myotonia in adults with non-dystrophic myotonic disorders. In randomized controlled trials, NaMuscla® (167 to 500 mg mexiletine/day) has been shown to significantly reduce myotonia compared to placebo, restoring 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 generally well tolerated[1,5].

About Lupin Limited

Lupin is an innovation led transnational pharmaceutical company developing and delivering a wide range of branded & generic formulations, biotechnology products and APIs globally. The Company is a significant player in the Cardiovascular, Diabetology, Asthma, Pediatric, CNS, GI, Anti-Infective and NSAID space and holds global leadership position in the Anti-TB segment.

Lupin is the 13th largest generics pharmaceutical company in terms of market capitalization (30th September 2018, Bloomberg) and the 8th largest generics pharmaceutical company in terms of revenues (30th June 2018, Bloomberg LTM) globally. The Company is the 3rd largest pharmaceutical player in the US by prescriptions for the Total Market (IQVIA MAT September 2018); 3rd largest Indian pharmaceutical company by global revenues (30th June 2018, Bloomberg LTM); 6th largest generic pharmaceutical player in Japan (IQVIA MAT September 2018) and 5th largest company in the Indian Pharmaceutical Market (IQVIA MAT September 2018).

For the financial year ended 31st March, 2018, Lupin's Consolidated sales and Net profits before exceptional items were at Rs. 155,598 million (USD 2.41 billion) and Rs. 13,934 million (USD 216 million) respectively. Please visit http://www.lupin.com for more information. You could also follow us on Twitter – www.twitter.com/lupinglobal

CIN: L24100MH1983PLC029442 Registered Office: Lupin Ltd, 3rd Floor, Kalpataru Inspire, Off Western Express Highway, Santacruz (East), Mumbai 400 055.

Press Release

For further information or queries please contact –

Pooja Thakran
VP – Corporate Communications
Email: poojathakran@lupin.com
Ph: +91-22-6640 2531 / 8291013225

Arvind Bothra
Head – Investor Relations
Email: arvindbothra@lupin.com
Ph: +91-22-6640 8237

**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. Mexiletine consumption in France at December 2018 (Data on File)
5. Myopath Survey (Lupin Data on File)
6. Statland et al. JAMA, 2012
7. Emery AE et al. Neuromuscular Disorders 1991