Press Release

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Orphan Drug NaMuscla® Receives European Commission Approval for the Treatment of Myotonia in Non-Dystrophic Myotonic Disorders

Zug, Mumbai, January 8, 2019 : Lupin is pleased to announce that the European Commission (EC) has approved NaMuscla® (mexiletine) for the symptomatic treatment of myotonia in adults with non-dystrophic myotonic (NDM) disorders. Non-dystrophic myotonic 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 outcomes[1,5].

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

The EC approval follows the positive opinion which was issued by the Committee for Medicinal Products for Human Use (CHMP), the scientific committee of the European Medicines Agency (EMA), in October 2018 and will apply to all 28 countries of the European Union, Norway, Iceland and Liechtenstein. The approval makes NaMuscla®, which recently had its orphan drug designation ratified by the EMA's Committee for Orphan Medicinal Products (COMP), the first treatment to be licensed throughout the EU for the symptomatic treatment of myotonia in adults with NDM disorders.

Lupin is preparing for the launch of NaMuscla®, which will occur in the initial markets of Germany and the UK in Q1 2019.

"We are delighted by the decision of the European Commission to approve NaMuscla®, making it the first treatment to be licensed across the EU for patients with non-dystrophic myotonia," **said Thierry Volle, President EMEA, Lupin.** "The EC approval represents a further important milestone for Lupin as we build a leading specialty pharma company focused on the development, registration and commercialization of science-based therapies and solutions for areas of unmet medical need. We are now closer to being able to provide patients with an effective treatment for myotonia symptoms and we look forward to launching the product in the first territories in Q1 2019."

The approval was based on a pivotal Phase III clinical study (MYOMEX[1]) which enrolled 25 participants who were diagnosed with non-dystrophic myotonic disorders and symptomatic myotonia, in addition to bibliographical references, including a randomized, placebo-controlled clinical study and an observational study, to support the efficacy and safety of mexiletine.

Today, more than 7500 people in Europe[2,3] living with NDM have limited access to a licensed treatment for myotonia which reduces 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 clinical experience among healthcare professionals, may result in harm to patients[4]. Lupin is also pursuing a paediatric investigation plan (PIP) for NaMuscla®.

"The EC approval of NaMuscla® is very good news and an important step forward for NDM patients across the EU living with the burden of symptomatic myotonia," **said Professor Christiane Schneider-Gold of St. Josef und St. Elisabeth Hospital / Neurologische Universitätsklinik (Bochum, Germany).** "The approval and commercialization of NaMuscla brings to an end the difficult off-label treatment challenges faced by these patients. With no licensed antimyotonic drug being available to date, many patients have lived without treatment. NaMuscla® fills an important, unmet clinical need for a licensed, efficacious treatment with a positive risk-benefit profile which is proven to significantly improve patient quality-of-life and disability caused by myotonia's lifelong impact."

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.

Non-dystrophic myotonias (NDM) are a sub-set of rare (prevalence of 1:100,000[2]), 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.

About 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 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

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**Safe Harbor Statement*

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