Press Release

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Lupin Neurosciences Announces Positive CHMP Opinion for NaMuscla™ for the Treatment of Myotonia in Non-Dystrophic Myotonic Disorders

Zug, Mumbai, October 19, 2018: Lupin Neurosciences, a specialty pharma division of Lupin Ltd, today announces that the Committee for Medicinal Products for Human Use (CHMP), the scientific committee of the European Medicines Agency (EMA), has adopted a positive opinion recommending the marketing authorization of NaMuscla™ (mexiletine hydrochloride) 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 of muscle relaxation 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].

The CHMP's positive opinion will now be reviewed by the European Commission (EC), which has the authority to approve medicines for the European Union (EU). The EC decision is expected within three months and will apply to all 28 countries of the European Union, Norway, Iceland and Liechtenstein. If approved, NaMuscla™ will be the first treatment licensed throughout the EU for the symptomatic treatment of myotonia in adults with NDM disorders. The therapy had already been awarded Orphan Drug designation.

“With this positive CHMP opinion we are now one step closer to offering NaMuscla™ to patients with non-dystrophic myotonia, for whom there are currently no licensed treatment options available across all EU countries”, **said Thierry Volle, President EMEA, Lupin.** “We eagerly await the next step; namely the European Commission’s decision, but the positive opinion represents an important milestone for Lupin Neurosciences as we build a leading specialty pharma company focused on the development, registration and commercialization of science-based therapies and solutions for neurological disorders that can restore function and significantly improve lives.”

The positive opinion from the CHMP 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 three controlled clinical studies, to support the efficacy and safety of mexiletine.

Today, more than 7500 people in Europe[1-2] living with NDM have limited access to a licensed treatment for myotonia which reduces the daily burden of this life-altering symptom. Limited access leads to inconsistent medication supply, administrative challenges and associated financial and geographical burdens, which, along with low awareness and clinical experience among healthcare professionals, may result in harm to patients[3].

“Today’s positive CHMP opinion in favour of the registration of NaMuscla™ (mexiletine hydrochloride) for the symptomatic treatment of myotonia in adults with non-dystrophic myotonic disorders is a very positive step towards meeting the significant unmet medical needs of this patient group across the European Union,” **said Prof. Dr. med. Benedikt Schoser, FEAN (Neurologische Klinik und Poliklinik, Klinikum der Universität München)**. "Untreated myotonia in NDM patients can lead to significant lifetime disability due to the stiffness, pain and fatigue associated with myotonic syndromes. Access to a consistent mexiletine formulation is the first step in removing barriers to myotonia treatment and optimizing care for these patients.”

About Lupin Neurosciences

Lupin Neurosciences is a division of Lupin Ltd. We are committed to improving the lives of patients affected by underserved neurological disorders. Our mission is to expand patient access to science-based therapies and solutions through building a global portfolio of specialty pharmaceuticals for development, registration and commercialization with partners and collaborators.

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 ultra-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, which often increasing in severity over time and persisting over the patient's lifetime, 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 hydrochloride)

NaMuscla™ is an antimyotonic agent which is under review by the European Medicines Agency to treat symptomatic myotonia in adults with non-dystrophic myotonic disorders. In randomized controlled trials, NaMuscla (200 to 600 mg/day) has 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 well tolerated[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 8th largest generics pharmaceutical company both in terms of market capitalization (30th June 2018, Bloomberg) and revenues (31st March 2018, Bloomberg LTM) globally. The Company is the 4th largest pharmaceutical player in the US by prescriptions (IQVIA MAT June 2018); 3rd largest Indian pharmaceutical company by global revenues (31st March 2018, Bloomberg LTM); 6th largest generic pharmaceutical player in Japan and 5th largest company in the Indian Pharmaceutical Market (IQVIA MAT June 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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