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Lupin's NaMuscla receives EC Approval

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Lupin has announced 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.

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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.

Thierry Volle, President EMEA, Lupin said, "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. 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 (MYOMEX1) 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.

Professor Christiane Schneider-Gold of St. Josef und St. Elisabeth Hospital / Neurologische Universitätsklinik (Bochum, Germany) said, “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.”

“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”, he added.

Today, more than 7500 people in Europe 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. Lupin is also pursuing a paediatric investigation plan (PIP) for NaMuscla®.