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Lupin signs distribution agreement for orphan drug NaMuscla

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Enables expanded patient access of rare disease medicine to treat myotonia symptoms in non-dystrophic myotonic disorders in three key territories

Pharma major Lupin Limited has announced that it has entered into distribution agreement with three companies for its orphan drug NaMuscla (mexiletine).

Exeltis Healthcare S.L, Cresco Pharma B.V and Macure Pharma ApS will commercialize NaMuscla for the symptomatic treatment of myotonia in adults with non-dystrophic myotonic (NDM) disorders in certain EU territories.

NaMuscula is the first and only licensed product for this indication. NDM 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 and clinical outcomes.

NaMuscla, which has been designated orphan drug status, received EU marketing authorization in December 2018. Under the agreements announced, Exeltis Healthcare S.L will commercialize NaMuscla in Spain and Portugal, Cresco Pharma B.V will commercialize NaMuscla in the Netherlands and Macure Pharma ApS in the Nordic countries.

Lupin will continue commercialization of NaMuscla in Germany and UK and will launch the product in Austria and France later this year.

Thierry Volle, President EMEA, Lupin said, “These distribution agreements represent an important milestone for Lupin as we roll out commercialization of NaMuscla® across Europe. Collaborating with partners that are highly effective in their focus territories ensures patients will receive the drug in as effective manner as possible. Lupin is committed to addressing the unmet needs of patients with NDM through the establishment of country-specific solutions and to ensuring patient access across Europe in alignment with national health authorities, healthcare providers and patient advocacy groups.”

Today, more than 7,500 people in Europe living with NDM have limited access to a licensed treatment for myotonia that can reduce 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 limited clinical experience among healthcare professionals due to rare nature of disease, may result in significant harm to patients.

Lupin recently obtained approvals to begin a paediatric trial as part of the paediatric investigation plan for NaMuscla and a post authorization [safety] study to address long-term safety and treatment efficaciousness on patient reported outcomes. Both trials will begin later this year.