

Newbury Pharmaceuticals Secures Approval for Macitentan film-coated tablets

Newbury Pharmaceuticals is pleased to announce the successful Marketing Authorization (MA) of Macitentan Newbury in Denmark as the first country in a Scandinavian registration procedure. Approvals in Sweden and Norway are expected to follow upon the completion of national reviews.

Macitentan is a medicine used for the long-term treatment of pulmonary arterial hypertension (PAH), a condition in which there is abnormally high blood pressure in the arteries of the lungs, causing symptoms such as breathlessness and fatigue.

Macitentan is used for adults, adolescents and children aged less than 18 years and bodyweight \geq 40 kg in whom PAH comes with moderate or marked limitations in physical activity (corresponding to WHO functional class II or III, respectively). Macitentan can be used alone or in combination with other PAH medicines.

Macitentan Newbury is a generic version of Opsumit®. The current annual value of the Scandinavian market is estimated to be 15 MEUR according to DLMI Nordic Pharma Insights.

“This rare disease medicine further strengthens the ambition to have a positive impact in society with products and technologies that contribute to the overall health care system and patient well-being. Based on this positive progress, we will proceed to launch this product within respective markets as soon as regulatory exclusivities and patents allow us.” says Mr. Lars Minor, CEO of Newbury.

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About Newbury Pharmaceuticals

Newbury Pharmaceuticals is building a pipeline of proprietary and licensed products with focus on specialty and branded products in the Nordics. Newbury aims to make a difference by offering treatment solutions within areas like oncology, rare diseases and neurology. The portfolio is built by leveraging experience and extensive international network. Newbury offers strategic partnerships of innovation for the benefit of the Nordic healthcare market.

Västra Hamnen Corporate Finance is the Company's Certified Adviser on Nasdaq First North and can be reached at ca@vhcorp.se or +46 (0) 40 200 250.

Attachments

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