Press Release
22 January 2025 09:00:00 CET

Newbury Pharmaceuticals Secures Generic Approval for Bosutinib tablets

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

Bosutinib is indicated for the treatment of adult patients with:

- newly-diagnosed chronic phase (CP) Philadelphia chromosome-positive chronic myelogenous leukaemia (Ph+ CML).
- CP, accelerated phase (AP), and blast phase (BP) Ph+ CML previously treated with one or more tyrosine kinase inhibitor(s) [TKI(s)] and for whom imatinib, nilotinib and dasatinib are not considered appropriate treatment options.

Bosutinib Newbury is a generic version of Bosulif. The annual value of the Scandinavian market is estimated to be 5,5 MEUR according to DLMI Nordic Pharma Insights.

> *"The successful approval of Bosutinib Newbury highlights Newbury's capability to offer a comprehensive portfolio within one of our focus areas oncology. 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.

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Attachments

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