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FDA has accepted for filing the first potential once-a-day nasal antihistamine

The New Drug Application (NDA) for a newly formulated higher strength azelastine nasal spray has now been accepted by the Food and Drug Administration (FDA) as complete for substantive review after initial evaluation.

"This product has the potential to become the first once-a-day nasal antihistamine in the U.S. Beside better tolerance with the new formulation it could also mean better compliance for patients. The product would contribute significantly to Meda's allergy franchise", said Anders Lönner, CEO Meda.

Meda has completed six phase III studies and a long-term safety study, involving more than 1,600 patients in total. In these clinical studies, the product demonstrated improvement in nasal symptom relief scores in patients with seasonal and perennial allergic rhinitis, and was well tolerated.

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MEDA AB (publ) is a leading international specialty pharma company. The company specialises in marketing and pharmaceutical development in late clinical stage. Acquisitions and long-term partnerships are fundamental factors that drive the company's strategy. Meda is represented by its own organisations in about 40 countries. Meda's products are sold in 120 countries worldwide. The Meda share is listed under Large Cap on the OMX Nordic Stock Exchange. Find out more, visit www.meda.se.

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