



ALK announces FDA Advisory Committee to review Grass AIT tablet

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Allergenic Products Advisory Committee meeting scheduled for 6 November 2013.

ALK (OMX: ALK B) today announced that the US Food and Drug Administration (FDA) has scheduled an FDA Allergenic Products Advisory Committee meeting to be held on 6 November 2013 to discuss the Biologic License Application (BLA) for the investigational grass allergy immunotherapy (AIT) tablet.

FDA advisory committees are panels of independent experts who advise the agency as they consider regulatory decisions. Advisory committee meetings are open to the public and are common for new drug classes and/or major pharmaceutical drugs under review.

In January 2013, ALK's partner for North America, Merck (NYSE: MRK), known as MSD outside the United States and Canada, submitted the BLA to the FDA for the disease-modifying tablet against grass pollen allergy. In March 2013, ALK and Merck announced that the BLA was accepted for review by the FDA.

Merck's application is based upon results from an extensive clinical development programme which demonstrates that treatment with grass AIT tablets reduces patients' allergy symptoms and their need for symptom-relieving medication. The data also shows that the grass AIT tablet provides a long-term effect for patients, which is sustained beyond the period of treatment. The product is marketed as GRAZAX® in Europe.

ALK's partnership with Merck covers the development, registration and commercialisation of a portfolio of allergy immunotherapy tablets in North America.

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