Company release No 14/2013

Hørsholm
8 May 2013

License application for ragweed allergy immunotherapy tablet accepted for review by FDA

Today, ALK's partner for North America, Merck (known as MSD outside the USA and Canada), announced that the U.S. Food and Drug Administration (FDA) has accepted the Biologics License Application (BLA) for its ragweed allergy immunotherapy tablet (AIT) for review. Merck submitted the BLA, for a tablet against ragweed allergy, to the FDA in March 2013.

The application to the FDA is based on results from an extensive clinical development programme. Data from the clinical trials have demonstrated that treatment with ragweed AIT reduces patients' allergy symptoms and their concomitant use of symptom-relieving medication and that the treatment is well tolerated. 20-30 million North Americans are estimated to suffer from seasonal ragweed allergy.

In March, the FDA accepted the BLA for grass AIT for review. Grass AIT is marketed by ALK in Europe as GRAZAX®.

"*The FDA is now reviewing two registration applications for allergy immunotherapy tablets against the most common pollen allergies in North America: ragweed and grass. This is a significant step forward in ALK's efforts to globalise allergy immunotherapy and help the many allergy sufferers in need of better treatment options,*" says Jens Bager, President and CEO, ALK.

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

Merck has also issued a news release, which follows in full, and which can also be found on the Merck corporate website: www.merck.com. This announcement does not change ALK's outlook for the financial year 2013.

ALK-Abelló A/S

Jens Bager
President and CEO

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About ALK

ALK is a research-driven global pharmaceutical company focusing on allergy prevention, diagnosis and treatment. ALK is the world leader in allergy immunotherapy – a unique treatment of the underlying cause of allergy. The company has approximately 1,800 employees with subsidiaries, production facilities and distributors worldwide. ALK has entered into partnership agreements with Merck (MSD outside the USA and Canada) and Torii to commercialise allergy immunotherapy tablets in North America and Japan, respectively. The company is headquartered in Hørsholm, Denmark, and listed on NASDAQ OMX Copenhagen. Find more information at www.alk.net.

About the partnership with Merck in North America

ALK has entered into a strategic partnership with Merck to develop, register and commercialise a portfolio of allergy immunotherapy tablets (AITs) against grass pollen, ragweed and house dust mite allergy in the USA, Canada and Mexico. Under the agreement, ALK will receive up to DKK 1.6 billion (USD 290 million) in milestone payments from Merck, of which approximately DKK 300 million has already been recognised in the years 2007-12. In addition, ALK is entitled to royalty payments on the net sales of the products on the North American market as well as payments for product supply. Merck will be responsible for all costs of clinical development, registration, marketing and sales of the products on the North American markets. ALK will be responsible for tablet production and supply.

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Merck Announces FDA Acceptance of Biologics License Application for Investigational Ragweed Pollen Sublingual Allergy Immunotherapy Tablet

WHITEHOUSE STATION, N.J., May 8, 2013 – Merck (NYSE: MRK), known as MSD outside the United States and Canada, today announced that the Biologics License Application (BLA) for its investigational ragweed pollen (*Ambrosia artemisiifolia*) sublingual allergy immunotherapy tablet has been accepted for review by the U.S. Food and Drug Administration (FDA). On March 27, Merck announced that the FDA had also accepted the BLA for its investigational Timothy grass pollen (*Phleum pratense*) sublingual allergy immunotherapy tablet. Merck expects the FDA's review for both to be completed in the first half of 2014.

The BLA for Merck's investigational ragweed pollen sublingual allergy immunotherapy tablet is supported by five studies evaluating the efficacy and safety of the tablet in adults, 18 years of age or older, with ragweed induced allergic rhinitis (with or without conjunctivitis).

"Merck has a long history of developing new therapies to help patients with allergic rhinitis," said Jeffrey A. Chodakewitz, M.D., senior vice president, interim franchise head, Respiratory & Immunology, Merck Research Laboratories. "This regulatory milestone for our investigational ragweed pollen sublingual allergy immunotherapy tablet represents another step in our continued commitment to offering potential new options to allergy specialists and their patients."

Merck's ragweed pollen sublingual allergy immunotherapy tablet is an investigational sublingual dissolvable tablet designed to help treat the underlying cause of allergic rhinitis by generating an immune response to help protect against the targeted allergen. Merck has partnered with ALK-Abello to develop its sublingual allergy immunotherapy tablets for ragweed pollen, timothy grass pollen and house dust mite in North America.

About Merck

Today's Merck is a global healthcare leader working to help the world be well. Merck is known as MSD outside the United States and Canada. Through our prescription medicines, vaccines, biologic therapies, and consumer care and animal health products, we work with customers and operate in more than 140 countries to deliver innovative health solutions. We also demonstrate our commitment to increasing access to healthcare through far-reaching policies, programs and partnerships. For more information, visit www.merck.com and connect with us on Twitter, Facebook and YouTube.

Forward-Looking Statement

This news release includes “forward-looking statements” within the meaning of the safe harbor provisions of the United States Private Securities Litigation Reform Act of 1995. These statements are based upon the current beliefs and expectations of Merck’s management and are subject to significant risks and uncertainties. There can be no guarantees with respect to pipeline products that the products will receive the necessary regulatory approvals or that they will prove to be commercially successful. If underlying assumptions prove inaccurate or risks or uncertainties materialize, actual results may differ materially from those set forth in the forward-looking statements.

Risks and uncertainties include but are not limited to, general industry conditions and competition; general economic factors, including interest rate and currency exchange rate fluctuations; the impact of pharmaceutical industry regulation and health care legislation in the United States and internationally; global trends toward health care cost containment; technological advances, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approval; Merck’s ability to accurately predict future market conditions; manufacturing difficulties or delays; financial instability of international economies and sovereign risk; dependence on the effectiveness of Merck’s patents and other protections for innovative products; and the exposure to litigation, including patent litigation, and/or regulatory actions.

Merck undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise. Additional factors that could cause results to differ materially from those described in the forward-looking statements can be found in Merck’s 2012 Annual Report on Form 10-K and the company’s other filings with the Securities and Exchange Commission (SEC) available at the SEC’s Internet site (www.sec.gov).

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