

Selskabsmeddelelse nr. 11/2013

Hørsholm
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Registreringsansøgning for tabletvaccine mod græspollenallergi accepteret til behandling af FDA

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ALKs partner i Nordamerika, Merck (MSD uden for USA og Canada) har i dag offentliggjort, at registreringsansøgningen for græs AIT er accepteret til behandling af de amerikanske sundhedsmyndigheder (FDA). Ansøgningen for den sygdomsmodificerende tabletvaccine blev indsendt til FDA i januar 2013. Produktet markedsføres i Europa som GRAZAX[®].

Mercks ansøgning er baseret på resultater fra et omfattende klinisk udviklingsprogram. Data fra de kliniske studier har påvist, at behandling med græs AIT reducerer patienternes allergisymptomer og deres behov for symptomdæmpende medicin samt giver en vedvarende langtidseffekt efter endt behandling.

Partnerskabet med Merck omfatter udvikling, registrering og kommercialisering af en portefølje af tabletvacciner i Nordamerika.

Merck har offentliggjort en pressemeddelelse, som findes i sin fulde længde på de efterfølgende sider. Meddelelsen kan desuden findes på Mercks hjemmeside: www.merck.com. Denne meddelelse ændrer ikke ALKs forventninger til regnskabsåret 2013.

ALK-Abelló A/S

Jens Bager
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Om ALK

ALK er en global, forskningsbaseret medicinalvirksomhed, der fokuserer på forebyggelse, diagnostisering og behandling af allergi. ALK er verdens førende virksomhed inden for allergivaccination (immunterapi) – en unik behandling af selve årsagen til allergi. Virksomheden har ca. 1.850 medarbejdere og datterselskaber, produktionsfaciliteter og distributører over hele verden. ALK har indgået partnerskabsaftaler med Merck og Torii om kommercialisering af tabletbaseret allergivaccination i henholdsvis Nordamerika og Japan. Selskabet har hovedkvarter i Hørsholm og er børsnoteret på NASDAQ OMX Copenhagen A/S. Læs mere på www.alk.net.

Om samarbejdet med Merck i Nordamerika

ALK har indgået et strategisk partnerskab med Merck om at udvikle, registrere og kommercialisere en portefølje af tabletbaserede allergivacciner (AIT) mod græs-, ragweed- og husstøvmideallergi i USA, Canada og Mexico. I henhold til aftalen er ALK berettiget til at modtage op til DKK 1,6 mia. (USD 290 mio.) i milepælsbetalinger fra Merck, hvoraf ca. DKK 300 mio. allerede er indtægtsført i årene 2007-12. ALK vil derudover modtage royaltybetalinger fra nettosalget af produkterne på det nordamerikanske marked samt betalinger for produktleverancer. Merck afholder alle omkostninger til klinisk udvikling, registrering, markedsføring og salg af produkterne på det nordamerikanske marked. ALK er ansvarlig for produktion og levering af tabletterne.



News Release

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

WHITEHOUSE STATION, N.J., March 27, 2013 – Merck (NYSE: MRK), known as MSD outside the United States and Canada, today announced that the Biologics License Application (BLA) for its investigational Timothy grass pollen (*Phleum pratense*) allergy immunotherapy tablet (AIT) has been accepted for review by the U.S. Food and Drug Administration (FDA). In March, the company also submitted a BLA to the FDA for its investigational ragweed pollen (*Ambrosia artemisiifolia*) AIT.

The BLA for Merck's grass pollen AIT is supported by Phase III trials that evaluated the safety and efficacy of the investigational product, including a long-term, multi-season trial.

"We are pleased to have achieved this important milestone in the development of our investigational grass pollen AIT, which, if approved, would represent a potential new option for allergy specialists to offer appropriate allergic rhinitis patients," said Jeffrey A. Chodakewitz, M.D., senior vice president, Global Scientific Strategy, franchise head, Infectious Diseases and interim franchise head, Respiratory & Immunology, Merck Research Laboratories.

Merck's grass pollen (*Phleum pratense*) AIT 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 targeted allergens. Merck has partnered with ALK-Abello to develop its grass pollen (*Phleum pratense*) AIT 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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