ALK to accelerate launches of ODACTRA™ in the USA / ACARIZAX® in Canada

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ALK (ALKB:DC / OMX: ALK B / AKABY / AKBLF):

- **The FDA has today transferred the US product licences for the SLIT-tablet portfolio to ALK allowing the company to give full speed on the US activities**
- **ALK will bring forward the North American launches of the house dust mite SLIT-tablet (ODACTRA™ in the USA, ACARIZAX® in Canada) from mid-2018 to Q4 2017**
- **ALK plans to expand pivotal Phase III clinical trial on allergic asthma to include US patients based on discussions with the FDA**
- **Full-year financial guidance for operating profit (EBITDA) has been revised due to accelerated investments to support the earlier launches of the HDM-SLIT tablet in the USA and Canada**

ALK today announced that the US Food and Drug Administration (FDA) has completed the transfer to ALK of the Biologics Licences for its tablet portfolio, including GRASTEK® and RAGWITEK® and the house dust mite SLIT-tablet ODACTRA™ (marketed as ACARIZAX® in Europe).

Following the transfer, investments in ALK's build-up in North America will be accelerated to bring forward the launches of the house dust mite tablet from mid-2018 to Q4 2017, which will pull forward costs for sales and marketing activities.

Carsten Hellmann, President and CEO of ALK, said: *"The addition of ODACTRA™ to ALK's portfolio is critical to our future strategy of offering a full range of tablets covering all the major respiratory allergies in North America. The transfer of the licences from our former partner was the final regulatory formality on our pre-launch checklist. Now it has been completed, we will move forward the investments related to the launches in the USA and Canada."*

Furthermore, following an initial dialogue with the FDA, ALK is now planning to expand a pivotal Phase III clinical trial, to include US patients. The trial will be initiated later this year to support approvals of ODACTRA™/ACARIZAX® for children with allergic asthma.

Full-year guidance has consequently been revised. EBITDA is now expected to be approximately DKK 225-250 million (previously: approximately DKK 300 million). Free cash flow is now expected at approximately minus DKK 700 million (previously: minus DKK 600 million or greater.) Full-year revenue is still projected at DKK 2.8-3.0 billion (2016: DKK 3.0 billion).

ALK-Abelló A/S

For further information please contact:
Carsten Hellmann, President & CEO
Investor Relations: Per Plotnikof, tel. +45 4574 7527, mobile +45 2261 2525
Media: Jeppe Ilkjær, tel. +45 7877 4532, mobile +45 3050 2014

About ACARIZAX®

In the USA, ODACTRA ™(ACARIZAX®) is approved as an allergen extract indicated as immunotherapy for house dust mite (HDM)-induced allergic rhinitis, with or without conjunctivitis, confirmed by in vitro *testing for IgE antibodies to* Dermatophagoides farinae *or* Dermatophagoides pteronyssinus *house dust mites, or skin testing to licensed house dust mite allergen extracts. ODACTRA™ is approved for use in adults 18 to 65 years of age. In Canada, ACARIZAX® is approved for the treatment of moderate to severe house dust mite-induced allergic rhinitis, with or without conjunctivitis, in adults aged 18 to 65. In Europe, ACARIZAX® has been approved in 14 countries. ACARIZAX® is also approved in Japan where it is licensed by ALK to Torii and marketed under the trade name MITICURE™, and in Australia where it is licensed by ALK to Seqirus. ACARIZAX® is also being developed for a number of other markets around the world including Russia, South-East Asia, Turkey, the Middle East and New Zealand. Altogether, clinical development activities for ACARIZAX® have involved more than 6,000 patients worldwide.*

About ALK

ALK is a research-driven global pharmaceutical company focusing on allergy prevention, diagnosis and treatment. ALK is a world leader in allergy immunotherapy — a treatment of the underlying cause of allergy. The company has approximately 2,300 employees, with subsidiaries, production facilities and distributors worldwide. ALK has entered into partnership agreements with Torii, Abbott, and Seqirus to commercialise sublingual allergy immunotherapy tablets in Japan, Russia and South-East Asia, and Australia and New Zealand, respectively. The company is headquartered in Hørsholm, Denmark, and listed on Nasdaq Copenhagen. Find more information at www.alk.net.