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ALK submits registration application for ragweed SLIT-tablet in Europe

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ALK ([ALKB:DC](#) / OMX: ALK B / AKABY / AKBLF) today announced that the European regulatory filing for its ragweed sublingual allergy immunotherapy (SLIT) tablet has been accepted for review by the relevant health authorities via the Decentralised Procedure, with Germany as the Reference Member State. The proposed indication is for the treatment of adult patients (18-65 years) with ragweed allergic rhinitis and/or conjunctivitis, despite use of symptom-relieving medication.

The data used in the filing are primarily drawn from the North American development programme which resulted in successful registrations in both Canada and the USA. In all, the programme involved 2,517 participants across five clinical trials that were conducted in North America, Hungary, Ukraine and Russia.

Carsten Hellmann, President and CEO of ALK, said: *“Today’s news represents another step forward in globalising our SLIT-tablet portfolio. Subject to approval, the introduction of the ragweed SLIT-tablet will be a useful addition to our European product range. In particular, strengthening our expansion markets in Eastern Europe, where ragweed allergy is most common.”*

Ragweed has been spreading in Europe since it first gained a foothold in the mid-1900s and, as it has spread, allergy to ragweed pollen has becoming increasingly common. Ragweed sensitisation varies greatly by country but is most significant in Eastern Europe. For example, in Hungary, it is estimated that more than 40% of the population is affected, whereas in Finland the figure is estimated to be just 2%.

In ragweed-affected areas, the threat on public health caused by ragweed appears to be enhanced due to the combined impact of air pollution and global warming, resulting in a higher allergenicity as a consequence of both an extended pollen season and a higher pollen load. Importantly, the threshold for eliciting clinical symptoms has been reported to be lower for the ragweed pollen when compared with other pollens. As with other respiratory allergies, such as house dust mite and grass pollen, ragweed-allergic patients often also have asthma.

The European regulatory review process is anticipated to take approximately 12 months so that, subject to approval, the first market introductions could take place from late 2018.

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About the ragweed SLIT-tablet

ALK's ragweed SLIT-tablet was initially developed for the North American markets as part of the now terminated partnership between ALK and MSD (known as Merck in the USA and Canada). Following a successful clinical development programme and subsequent regulatory approvals, the product was launched in the USA and Canada in 2014 under the brand name RAGWITEK®.

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.