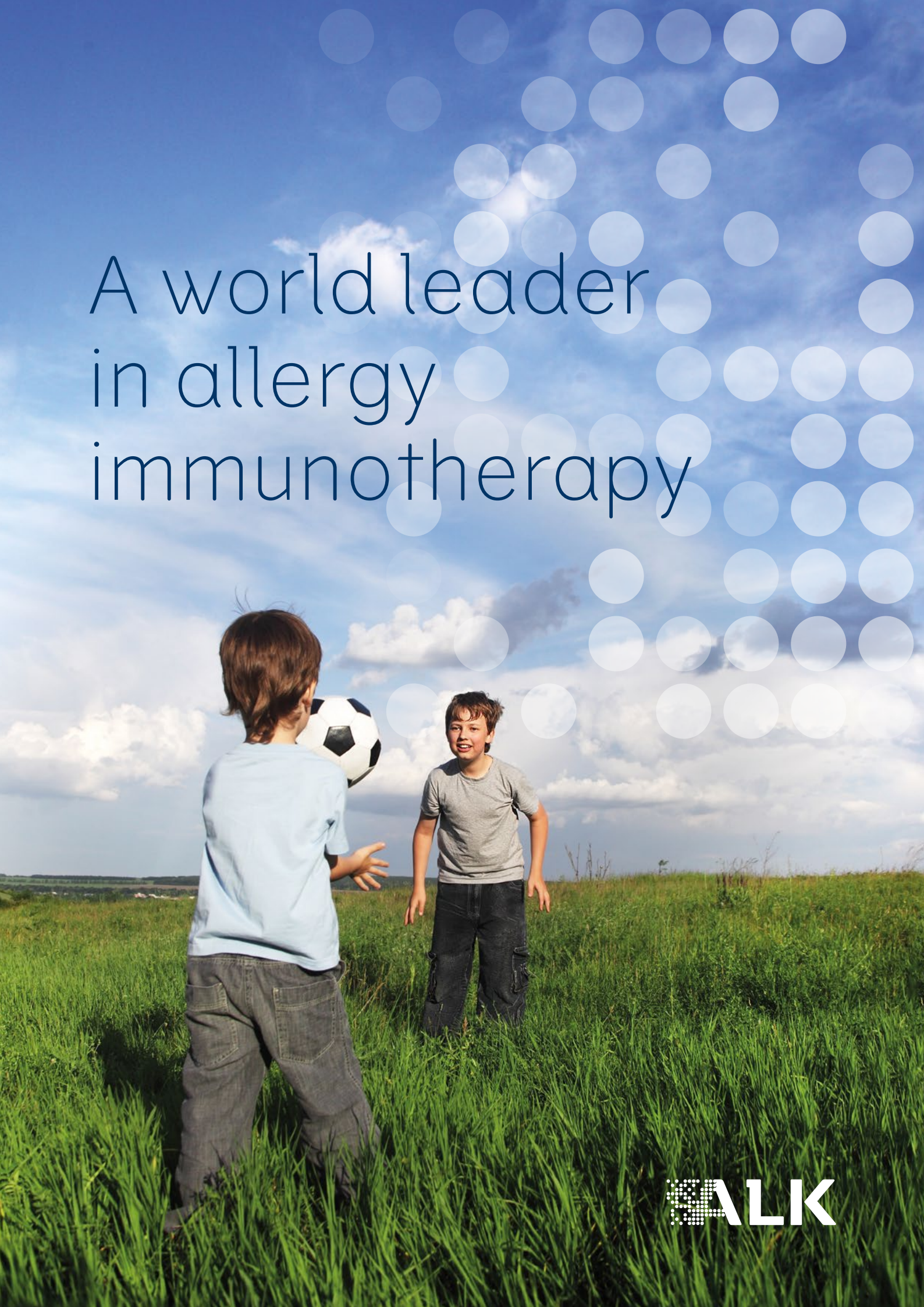
A world leader in allergy immunotherapy



ALK

Milestones in the history of ALK

ALK was founded on 9th June 1923 when pharmacist Peter Barfod and physician Kaj Baagøe recorded the **first pharmaceutically manufactured allergy preparation**. The product was designed to treat allergic reactions to goose feathers – neither Barfod or Baagøe realised that it was actually dust mites in duvets rather than goose feathers that were the true causes of the allergies they were investigating.

Since 1923, **ALK has consistently devised and developed major advances for the treatment of allergy.** In recent years, ALK and its global partners have invested substantially in the research and development of new, evidence-based sublingual allergy immunotherapy (SLIT) tablets covering the majority of the respiratory allergies – house dust mite, grass pollen, tree pollen and ragweed pollen, as well as Japanese cedar pollen, which is a major cause of allergy in Japan.

In parallel, ALK's dedicated research and development has shown that **allergy immunotherapy addresses the underlying cause of the allergy rather than just treating the symptoms** and that it potentially prevents the development of asthma. With its latest product, ALK has become the first and only company to develop and launch a house dust mite SLIT-tablet which is indicated for usage in both allergic rhinitis and allergic asthma. Recently, ALK also disclosed data from a long-term clinical trial into asthma prevention in children suffering from grass pollen allergy which showed that ALK's tablet based allergy immunotherapy treatment for grass pollen allergy, significantly reduced the proportion of children experiencing asthma symptoms, an effect which was sustained for two years after end of treatment.

1923 – Peter Barfod and Kaj Baagøe produce the first pharmaceutically manufactured allergen extract at the Copenhagen University Hospital

1972 >1976 – ALK develops the technique to accurately identify the proteins that provoke allergies and a standardised process for manufacturing allergen extracts

1978 – The world's first standardised allergy immunotherapy is launched by ALK

1990 – ALK launches the world's first sublingual allergy immunotherapy drops (SLIT-drops)

1990 >1995 – ALK collaborates on research that shows allergy immunotherapy decreases the risk of developing asthma in children with allergic rhinitis

2006 – ALK's SLIT-tablet for grass is approved in Europe as the world's first sublingual allergy immunotherapy tablet

2009 – ALK's SLIT-tablet for grass is the only SLIT-tablet to be approved as a disease-modifying treatment for grass pollen allergy

2015 – ALK's SLIT-tablet for house dust mite allergy, is the first SLIT-tablet approved for both allergic rhinitis and allergic asthma

2016 – Trial in children demonstrates that ALK's SLIT-tablet for grass reduces the risk in development of asthma symptoms and/or use of asthma medication in children with grass pollen allergic rhinitis

Pioneering allergy research

Committed to innovation, ALK develops products which address allergic rhinitis and allergic asthma in entirely new ways.

In the 1970s, ALK was the first company in its field to standardise the production of allergen extracts for use in allergy immunotherapy.

In the 1990s, ALK was **the first company to launch sublingual allergy immunotherapy (SLIT) drops for allergy treatment** - a decisive step towards making allergy immunotherapy more convenient for patients.

And in the 2000s, ALK developed **the world's first sublingual allergy immunotherapy tablet (SLIT-tablet)**, against grass pollen allergy. Later came SLIT-tablets against ragweed and house dust mite allergies.

Looking ahead, ALK's R&D pipeline has the potential to further redefine the treatment of allergic rhinitis and allergic asthma. Hence, focus remains on completing a SLIT-tablet portfolio covering the most common global allergies and further documenting the tablets' benefits in the treatment of allergic asthma and asthma prevention. Furthermore ALK will also increasingly add resources **to explore new technologies for the next generation of allergy immunotherapy.**

ALK's research and development focuses on three areas

Development of tablet-based allergy immunotherapy treatments against the most common allergies worldwide

Application of allergy immunotherapy to prevent the onset of respiratory allergy if treatment is given early in life

Pioneer research into the link between respiratory allergies and asthma

ALK's pipeline includes a portfolio of allergy immunotherapy tablets against five of the most common respiratory allergies:

Tablet based immunotherapy	Research	Preclinical	Phase I	Phase II	Phase III	Marketed
Grass	●	●	●	●	●	●
Ragweed	●	●	●	●	●	●
House dust mite	●	●	●	●	●	●
Japanese cedar	●	●	●	●	●	
Birch tree	●	●	●	●	●	
Next generation allergy immunotherapy	●					

ALK: A unique production approach

As a company whose products touch the lives and affect the well-being of people around the world, ALK is committed to maintaining the highest standards. This includes the entire manufacturing process, from the collection of raw materials such as pollen, to the manufacturing of the finished allergy immunotherapy products.

THERE ARE **FOUR KEY STEPS** TO ENSURING ALK'S PRODUCTS MEET THE REQUIRED QUALITY STANDARDS:

STEP 1:
Raw materials

Natural allergens such as grass pollen and house dust mites are the main ingredients of ALK's products and every year the company grows, collects and harvests several tonnes of allergens. House dust mites are grown in pure cultures.

STEP 2:
Active Pharmaceutical Ingredient (API) production

Handling natural allergens requires thorough analysis, standardisation and quality control processes. This ensures that the biological variation that will always be present in a natural product does not affect the quality of the finished product. It also ensures that it is possible to reproduce the product at any time.

STEP 3:
Finished production

The active pharmaceutical ingredient is purified in our own production facilities. Subsequently, the active ingredient is formulated as subcutaneous injections, sublingual drops or sublingual tablets.

STEP 4:
Packaging and distribution

Following careful quality control, the finished products are labelled, packaged and distributed.

ALK works continuously to ensure its production process is as efficient and safe as possible. As a consequence, SAP was implemented as ALK's new Enterprise Resource Planning (ERP) system in 2014.

About ALK

Who we are

ALK is a global, research-driven pharmaceutical company that focuses on allergy prevention, diagnosis and treatment. The company specialises in allergy immunotherapy – a unique treatment, which not only reduces allergic symptoms but also treats the underlying cause of a specific allergy.

ALK was founded in 1923 and has since then been working to **improve quality of life for allergy patients whose disease continues to impact them**.

The company has approximately 2,300 employees, with subsidiaries, production facilities and distributors worldwide. ALK is headquartered in Denmark and listed on NASDAQ Copenhagen (OMX: ALK B).

What we do

ALK recognises that allergic disease seriously impacts everyday life, whether it be at home, work or school. As a world leader in allergy immunotherapy, ALK works to improve quality of life for the many allergy sufferers whose disease remains uncontrolled despite the use of symptom-relieving medication, by developing products that treat the cause of the allergy and provide long-lasting relief.

ALK offers allergy immunotherapy products in the form of sublingual tablets, injections, sublingual drops. Tablet based immunotherapy is the newest, best documented and most convenient form of treatment.

In addition, ALK also produces an adrenaline auto-injector for the treatment of severe allergic reactions (anaphylaxis) and also manufactures products used in the diagnosis of allergies.

About ALK

Why our work is important

Allergic disease is one of the world's most common chronic conditions, affecting millions of people globally. Allergic rhinitis alone affects an estimated 400-500 million people worldwide, approximately 10% of whom experience a debilitating form of their condition. Left untreated, allergic rhinitis is considered to be one of the major risk factors in the development of asthma[1].

Allergy also imposes a significant cost on society, through lower productivity, increased sick leave, as well as significant healthcare costs. For example, a study from the USA has shown that allergic rhinitis causes a greater loss of annual productivity than stress, migraine, depression, arthritis/rheumatism, anxiety disorder, respiratory infections, hypertension/high blood pressure, diabetes, or coronary heart disease[2,3].

Our future

As a treatment concept, allergy immunotherapy is now more than 100 years old. **As a constant pioneer in the field allergy immunotherapy, ALK has challenged and pushed the boundaries of allergy treatment.** Today, allergy immunotherapy is entering a new era with the advent of more convenient tablet-based treatments, first introduced by ALK in 2006.

ALK is reinvesting a large part of its annual revenue into the discovery and development of future medicines. At the same time, the company is working to raise awareness about new treatment options among healthcare professionals and patients alike.

ALK FACT BOX:

Present in over
32 countries
in the world

1.5 million people
in the world are using ALK products

2,300 employees

40%
Global market share in 2016

25% organic growth
in 2016

1. (Bufe A, Eberle P, Franke-Beckmann E, et al. Safety and efficacy in children of an SQ-standardized grass allergen tablet for sublingual immunotherapy. J Allergy Clin Immunol 2009;123:167-73.)
2. (Lamb CE, Ratner PH, Johnson CE, et al. Economic impact of workplace productivity losses due to allergic rhinitis compared with select medical conditions in the United States from an employer perspective. Curr Med Res Opin. 2006;22:1203-10.
3. Meltzer EO, Gross GN, Katial R, et al. Allergic rhinitis substantially impacts patient quality of life: findings from the Nasal Allergy Survey Assessing Limitations. J Fam Pract. 2012;61(2):S5-10.)

ALK : Addressing a global problem

Respiratory allergy is an umbrella term that includes **allergic rhinitis** (where the inside of the nose and nasal passages become irritated and inflamed) and **allergic asthma** (where the lower airways of the lungs become inflamed and swollen). The condition can worsen over time if not treated – e.g., **allergic rhinitis is considered to be one of the major risk factors in the development of asthma if left untreated**[1]. The prevalence of respiratory allergies has increased over recent decades[2] and is rising dramatically in both developed and developing countries[3].

Globally
400-500 million
people are affected by allergic rhinitis

Globally an estimated **400- 500 million people are affected by allergic** rhinitis and **40% of these are children**[3]. It is estimated that 10- 20% of allergic rhinitis sufferers have a condition which is not well controlled and that only one in ten of these receive allergy immunotherapy treatment.

40% of these are children

House dust mite allergy is the most common respiratory allergy, affecting around half of all people with an allergy[4]. Furthermore, **half of patients with house dust mite respiratory allergy suffer from both allergic rhinitis and allergic asthma**[5,6], which calls for a need to address both conditions.

~10-20%
of people with allergic rhinitis are not well controlled

At ALK we recognise the impact living with not well controlled allergy has on everyday life at home, work and school. **Our commitment is to continue to evolve our products beyond symptom control to give allergy sufferers long-lasting relief with real-life tested products and solutions.**

To deliver on our commitment to patients **ALK has entered into partnership agreements** with Torii, Abbott and Seqirus to commercialise – in particular – its sublingual allergy immunotherapy (SLIT) tablets in Japan, Russia and South-East Asia, and Australia and New Zealand, respectively.

Only
1 in 10 people
with not well controlled allergic rhinitis receive allergy immunotherapy

1. Bufe A, Eberle P, Franke-Beckmann E, et al. Safety and efficacy in children of an SQ-standardized grass allergen tablet for sublingual immunotherapy. J Allergy Clin Immunol 2009;123:167-73.
2. Bousquet J, Khaltaev N, Cruz AA, et al. Allergic rhinitis and its impact on asthma (ARIA) 2008 update (in collaboration with the World Health Organisation, GA(2)LEN and AllerGen). Allergy. 2008;63(Suppl 86):8-160.
3. Pawankar RS, Sanchez-Borges M, Bonini S, et al. Allergic rhinitis. In: Pawankar RS, Canonica GW, Holgate ST, Lockey RF, eds. World Allergy Organization (WAO) White Book on Allergy, 2011:27-30.
4. Chen KW et al. J Allergy Clin Immunol 2012;130:435-43.
5. Linneberg A et al. Allergy 2002; 57:1048-52.
6. Knudsen TB et al. J Asthma 2009;46:A91-4.

ALK's owners contribute to society

Although traded on the NASDAQ Copenhagen (OMX: ALK B), ALK boasts an unusually stable ownership, with two shareholders having notified shareholdings of 5% or more as of November 2017.

Founded in 1954, **The Lundbeck Foundation is the largest and controlling shareholder of ALK, owning 67% of the votes** (40% of the capital). In addition, the foundation is the majority shareholder in two other major Danish companies, Lundbeck and Falck, and manages securities of about DKK 15 billion.

The **Lundbeck Foundation is an industrial foundation whose activities make a difference for people's health and well-being through its support for scientific research**. The foundation's return on its investment in ALK contributes to this purpose.

The Lundbeck Foundation is one of the largest industrial foundations in Denmark with a total market value of its commercial activities of approximately DKK 50 billion and an annual spend of DKK 400-500 million in grants to support biomedical independent research of the highest international quality.

The foundation also invests in European and American life science companies and supports a range of early stage investment projects through Lundbeckfonden Emerge.

EXAMPLES OF GRANTS FROM THE LUNDBECK FOUNDATION

2013 Allergy researcher Jacob Pontoppidan Thyssen examines in a five-year research project funded by Lundbeck Foundation how asthma can develop in the lungs and allergies in the mucous membranes and skin because something has penetrated the skin elsewhere on the body.

2014 Pediatrician Klaus Bønnelykke from the Childhood Asthma Center COPSAC received a Lundbeck Foundation Fellowship grant of DKK 10 million to map the genetic control of asthma, thereby improving the quality of both prevention and treatment.

2015 Immunologist Vasileios Bekiaris received a Lundbeck Foundation Fellowship grant of DKK 10 million. The money will be used to identify how the immune system's white blood cells recognize the chemical signals from sclerosis-affected tissue.

OVERVIEW OF THE LUNDBECK FOUNDATION

DKK 442 MILLION

Lundbeck Foundation's spend on grants to support research in 2015

CONTROLLING SHAREHOLDER

The Lundbeck Foundation is the largest and controlling shareholder of ALK, owning 67% of the votes (40% of the capital)

DKK 126 MILLION

The foundation has supported research in allergy and asthma with this amount over the past 10 years.