

Research & Development

Expansion of R&D pipeline to serve more people with allergy

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ALK - a pioneer
in molecular and
clinical allergology

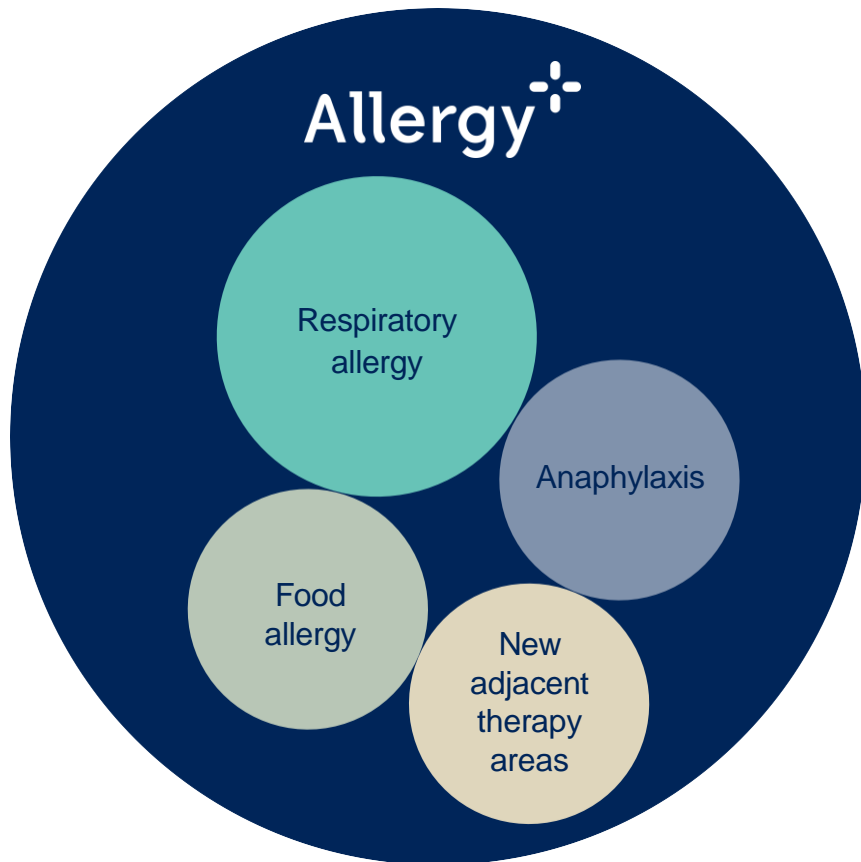
Proven
development
competencies from
previous SLIT-
tablet programs

A track record of
successful global
partnerships
contributing to
innovation



Ample opportunities to
leverage ALK's core R&D
capabilities and scientific
leadership to amplify
innovation and serve more
people with allergy

Remaining unmet needs in allergy call for more innovative solutions to improve outcomes



Respiratory allergy

Many patients have uncontrolled disease despite symptom-relieving treatment

Intervention from young age is needed to combat the atopic march¹

Anaphylaxis

Massive under-utilisation of adrenaline auto-injectors

Optimal treatment is often impeded by late intervention and use

Food allergy

Life-threatening condition with high prevalence among children

Peanut & tree nut allergy account for the highest rate of anaphylaxis

New adjacent therapy areas

Indications with high unmet needs and inadequate treatment options

Ample opportunities to make a real difference to people

1. Atopic March: The progression of allergic diseases beginning early in life

R&D vision | Invest in building a balanced pipeline through internal & external innovation to bolster long-term growth

Strategic priorities

1

Expand leadership in respiratory allergy, build portfolio in anaphylaxis & food allergy and expand pipeline into adjacent TAs

2

Leverage R&D capabilities to increase internal innovation

3

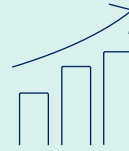
Grow and advance the pipeline through external innovation and partnerships

4

Deploy data, digital tools and AI throughout drug development



2028 ambitions



Increased number of clinical pipeline assets



Balanced pipeline with regards to innovation potential, development risk, value potential, therapy area, development stage, etc.



Bring more assets from research to development to launch

Today's pipeline supports ALK's mid-term growth targets – yet further innovation needed for longer term ambition

Discovery



Phase 1/2



Phase 3/4



Regulatory



Un-disclosed targets

Un-disclosed asset
mast cell disease

Peanut tablet
food allergy

Genesis
anaphylaxis

ACARIZAX[®] China

Un-disclosed targets

Un-disclosed asset
food allergy

GRAZAX[®] Japan
(Torii Partnership)

ACARIZAX[®]
paediatric label
extension

Tree nut tablet
food allergy

ITULAZAX[®]
paediatric label
extension

Explore relevant partnerships



Explore business development and licensing opportunities

- Potential for multiple indications
- Mast cell disease
- Food allergy
- Respiratory allergy
- Anaphylaxis

Translating corporate strategic priorities to R&D pipeline activities

Respiratory allergy

Maximise the value of the respiratory portfolio through LCM

Pioneer disease modification and prevention of the atopic march

Enhance evidence generation by leveraging data and AI

Anaphylaxis

Committed to build portfolio

Progress Genesis development

Develop innovative solutions internally and through partnerships

Food allergy

Advance peanut AIT program

Progress pipeline projects with new mechanism of actions

Utilise data and AI to improve development programs & outcomes

New adjacent therapy areas

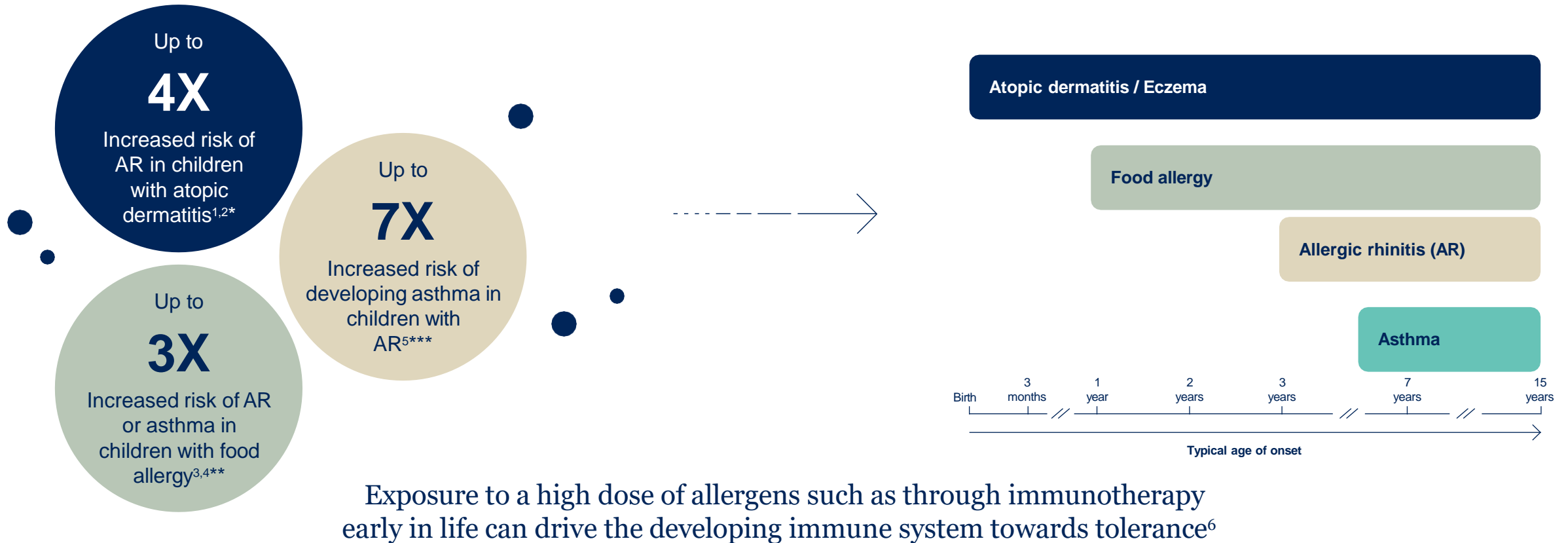
Progress new modalities in discovery

Research in key mechanisms (e.g. IgE memory B cells, mast cells)

Build pipeline through internal & external innovation

Respiratory allergy is a chronic progressive disease often leading to multiple co-existing disease manifestations

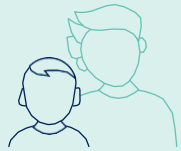
Intervention in early childhood may prevent disease progression



Note. The allergic march is defined as the progression of one allergic manifestation to another over time

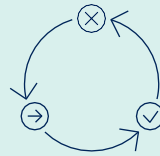
1. von Kobyletzki et al. *BMC Dermatology* 2012, 12:11; 2. Schoos et al. *Allergy*. 2022;77(4):1254-62, 3. Hill et al. *BMC Pediatrics* 2016;16:133; 4. Goksör et al. *Acta Pædiatrica* 2016; 105:1472–795. 5. Burgess et al. *J Allergy Clin Immunol* 2007;120:863-9; 6 Du Toit et al. *N Engl J Med*. 2015;372(9):803-13. doi: 10.1056/NEJMoa1414850. *vs. children with no eczema; Early onset meaning <1 years old; **vs. children without food allergy; ***vs. children without AR

Strengthen AIT leadership through paediatric indications and focused LCM



Paediatric indications

- Two successful Phase 3 paediatric clinical trials completed in 2023
- Regulatory filings to obtain paediatric indications globally for HDM and tree tablets



Focused Life Cycle Management

- Geographical expansion of the tablet portfolio, e.g.
 - GRAZAX[®] in Japan (Torii Partnership)



Evidence generation

- Strengthen evidence around burden of disease, disease modification and new indications
- Use AI to generate new evidence by leveraging unique data foundation and strong data science capabilities

We are developing the most complete portfolio globally in AIT, supported by a strong body of evidence

Data and AI enhance R&D innovation and development efficiency in respiratory allergy and beyond...

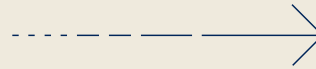
Unique data foundation

- 21 Phase 3 clinical trials
- 25+ years of lab data
- 100,000+ biobank samples
- 6m+ real world data from **Klarify universe**

Data Science track record

- Effect of SLIT on asthma
- Identification of memory B-cells
- Biomarker discovery
- Clinical data science
- Machine learning partnerships

ALK-wide data & AI platform in **2024**



Clinical Development

Smart trial designs
AI assisted authoring
Data mining

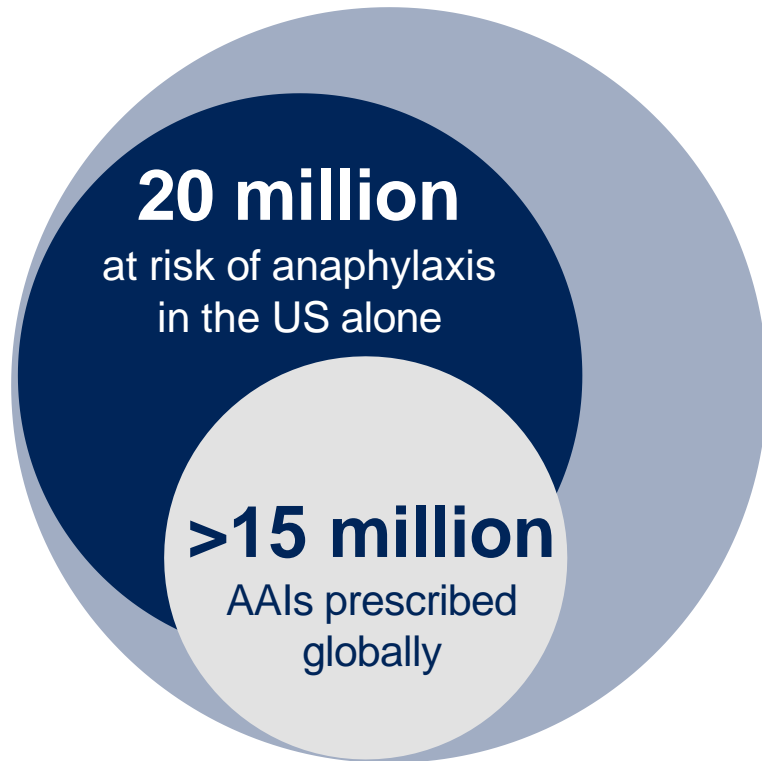
Research & Drug Discovery

Target discovery
In silico analyses

Medical Affairs

Predict and assist patient journeys
HCP engagement

In a changing landscape, ALK remains dedicated to improving the life of people at risk of anaphylaxis - with a global portfolio of innovation



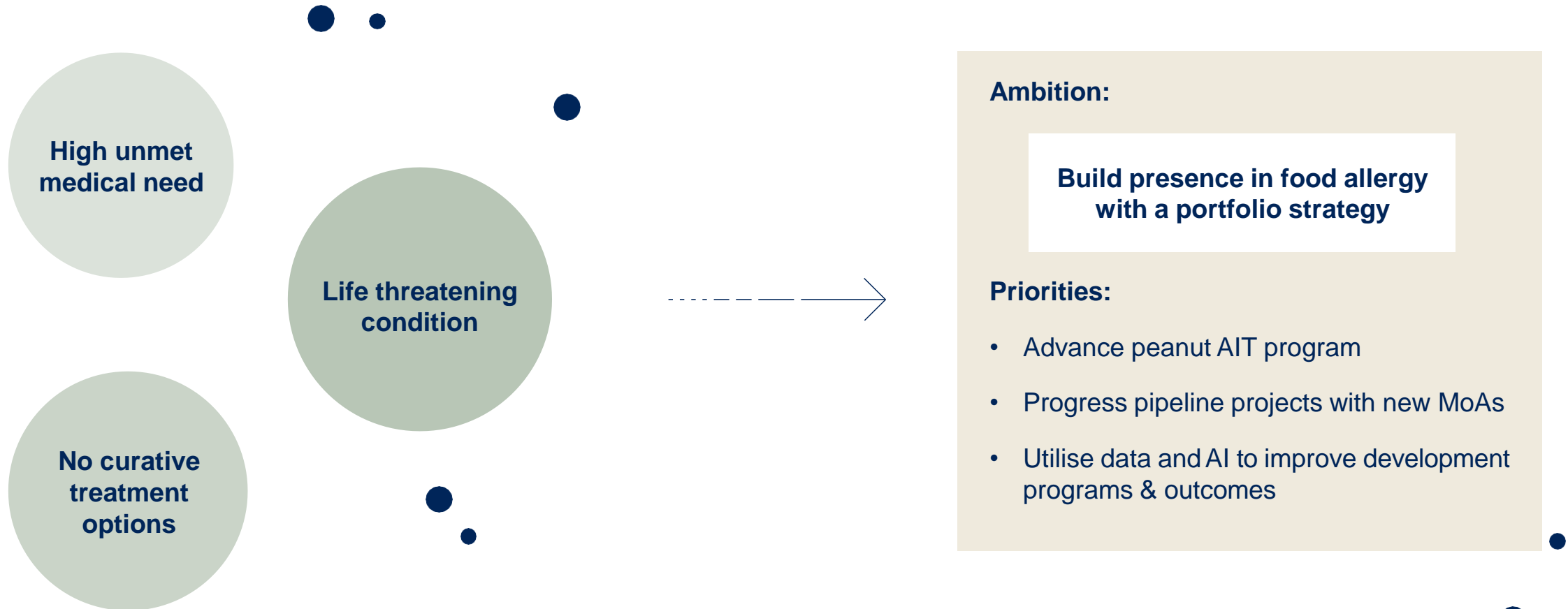
ALK is uniquely positioned in Anaphylaxis ...

- Global company with strong legacy in anaphylaxis management
- Unmatched disease understanding and scientific leadership within severe allergies

.. to bring innovation to market and extend patient reach

- Current portfolio consisting of Jext, and the next-generation autoinjector, Genesis
- Committed to develop new patient-friendly solutions internally and through collaborations

Despite recent advancements, the unmet need in food allergy remains high with notable gaps in the treatment landscape

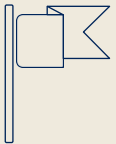


Drug development in food allergy is leveraging ALK's core R&D capabilities – starting with Peanut as point of entry

ALK core capabilities



Deep biology understanding



World class experts in molecular and clinical allergology



Proven development competencies from previous SLIT-tablet programs

Strategic considerations

Establish presence in Peanut allergy

- Build on legacy in AIT with the **SLIT platform**
- SLIT tablets shown to be safe, efficacious and suited for **paediatric use**
- Unique **MoA**

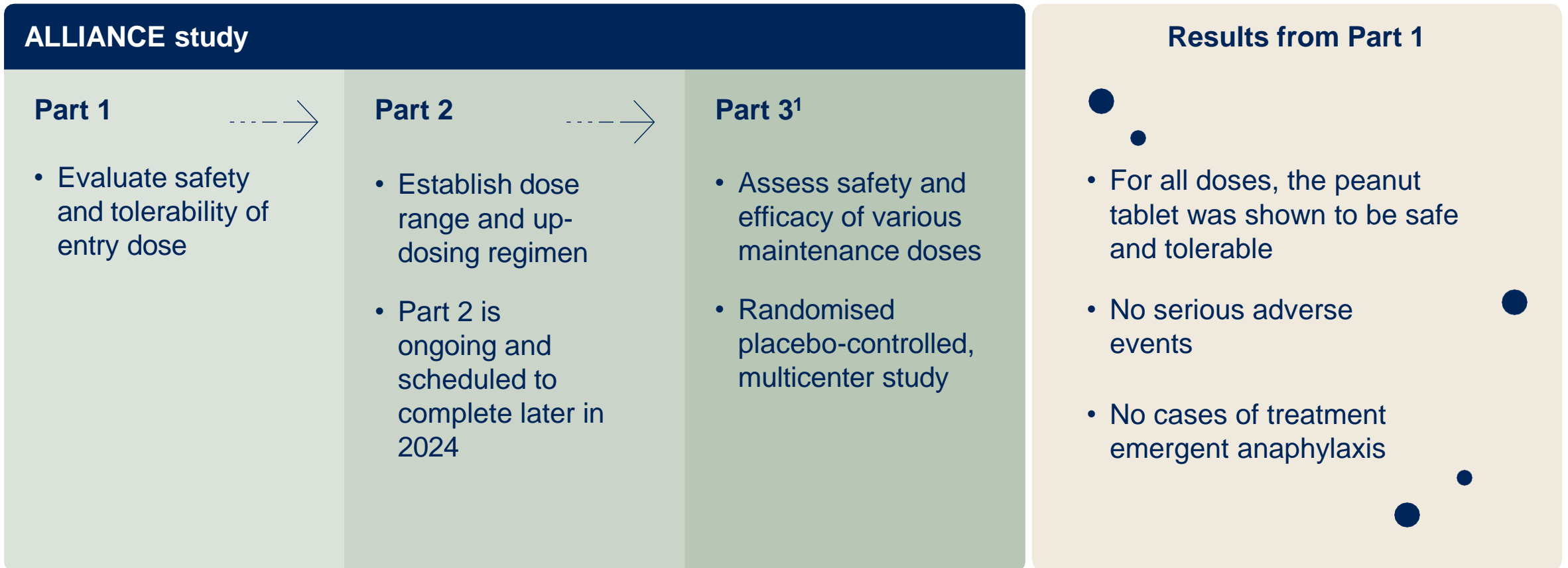
Build pipeline in food allergy

- Introduce **novel concepts and new modalities**
- Expand from **peanut allergy to food allergy**
- Address the **highest unmet needs**

Bridge to new indications

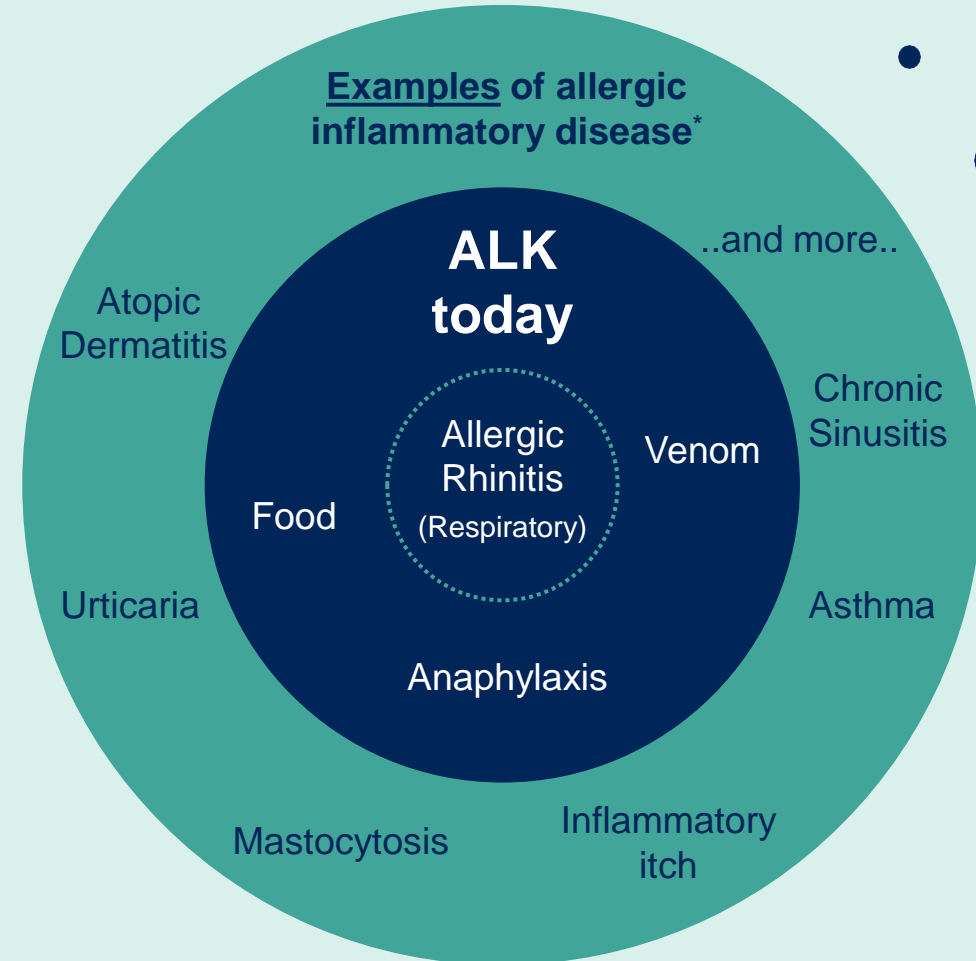
- Explore potential for **prevention of new allergies**
- Unfold potential for **long-term disease control**
- Pursue **pipeline-in-a-product**
- Assess potential in **adjacent indications** with strong ALK fit

ALLIANCE study with Peanut tablet progressing as planned and amended with seamless Phase 1-2 design for an early efficacy read-out



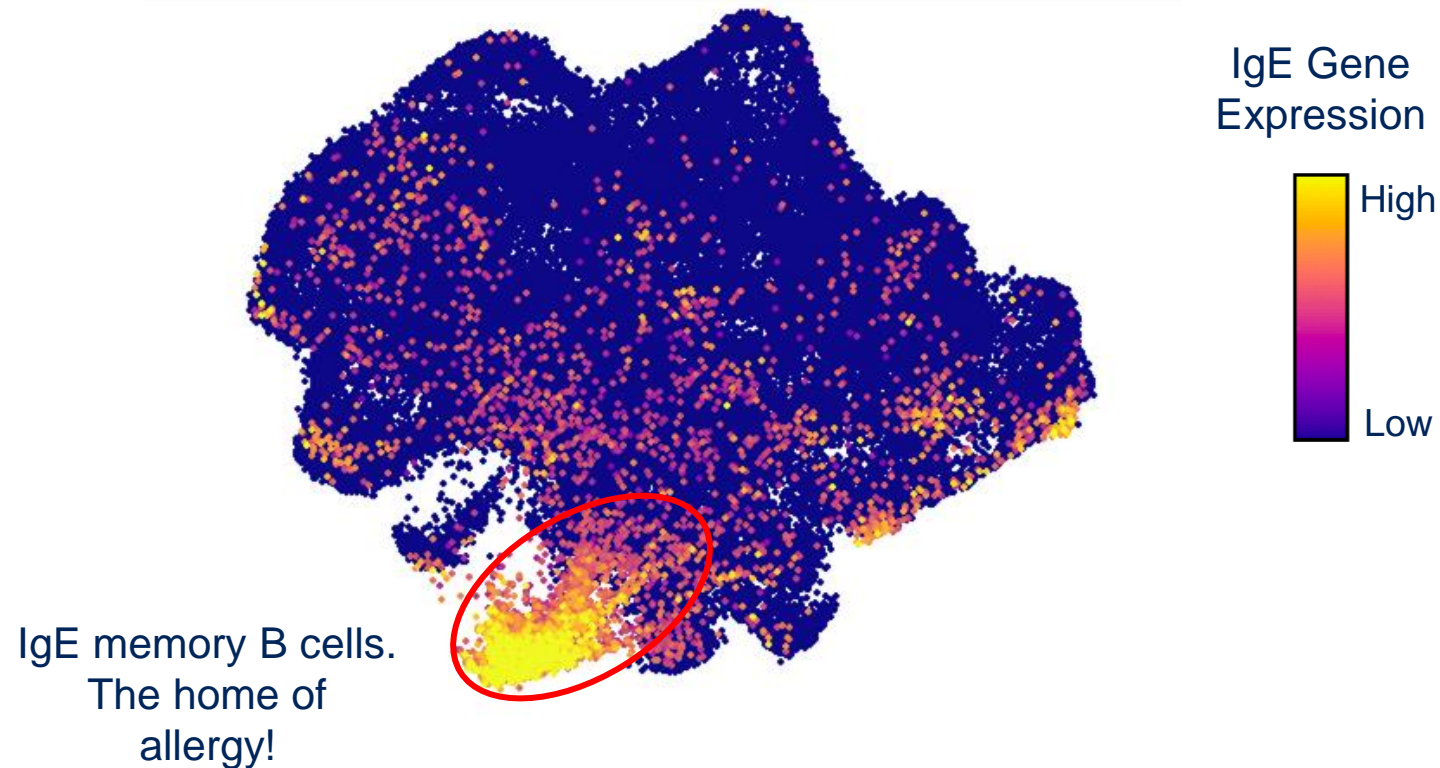
Note: 1. Part 3 is contingent upon a successful outcome of Part 2

Gradual expansion into a broader Therapy Area landscape

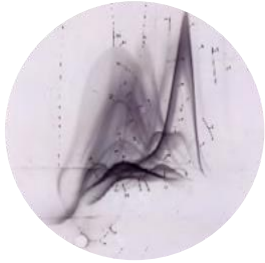


* Non-exhaustive list of examples

Immunomodulation takes center stage - New technologies lead to **breakthrough discoveries** in allergy



Building on decades of innovative research at ALK



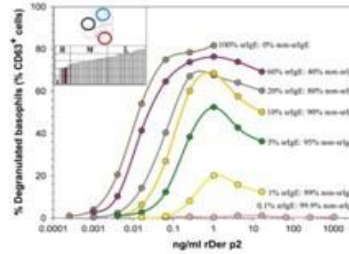
1984 ○

Setting global standards for extract quality in AIT



○

Pioneering molecular and structural biology of allergens



○

Seminal work on IgE triggering by allergens



○

Building the SLIT tablet portfolio in respiratory allergy

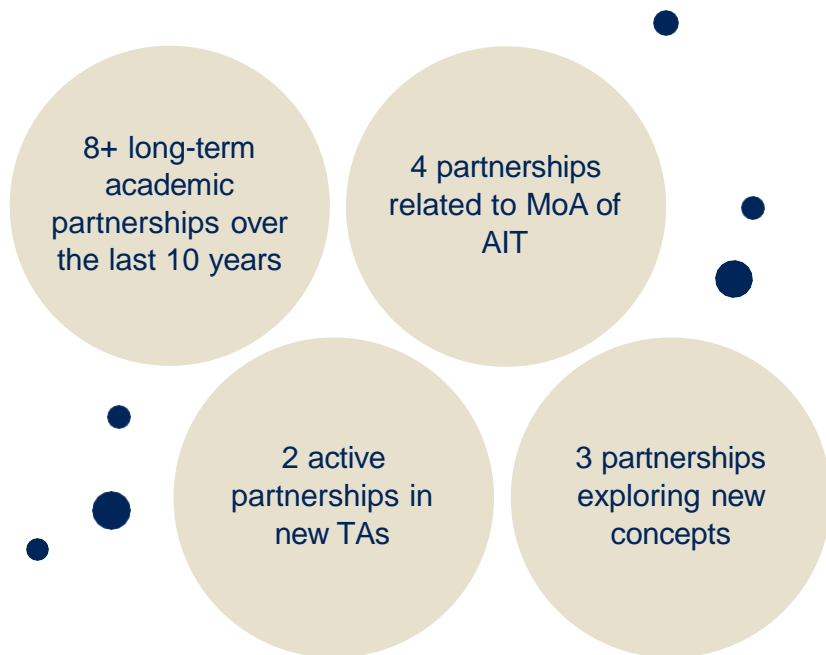


○ 2024

IgE memory B cells, the home of allergy

Leveraging global academic partnerships to propel innovation and build pipeline

Academic partnerships within the last 10 years



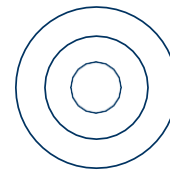
Selected key highlights of partnerships



IgE memory B cell

Respiratory allergy

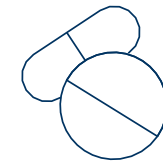
SLIT mode of action



New indications & Target discovery



Peptide immunotherapy



SLIT-tablet

Strengthen innovation through collaborations

Academic collaborations fueling initiation of the Peanut SLIT tablet program



Industry advisor
for DTU FOOD
project



Minor partner in DTU
FOOD project sponsored
by Innovation Fond DK



McMaster collaboration in
food allergy immunobiology
+ SickKids collaboration on
tree nut allergy



Main industry partner in DTU
FOOD project sponsored by
Innovation Fond DK

Initiation of internal
research in peanut allergy



Initiation of CMC development
of peanut SLIT tablet



Initiation of Phase I clinical
trial with peanut SLIT-tablet

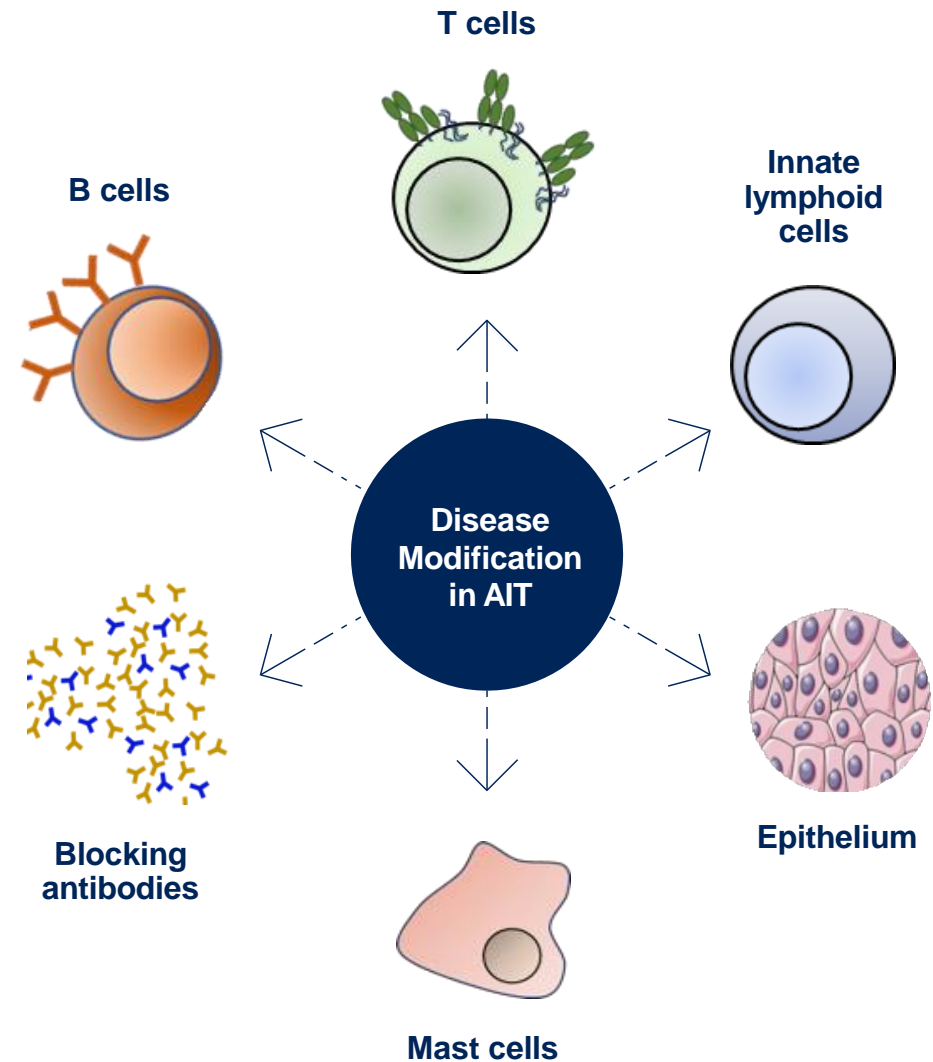


Note: SLIT = Sublingual Immunotherapy

ALK's research and drug discovery at present

ALK core competences

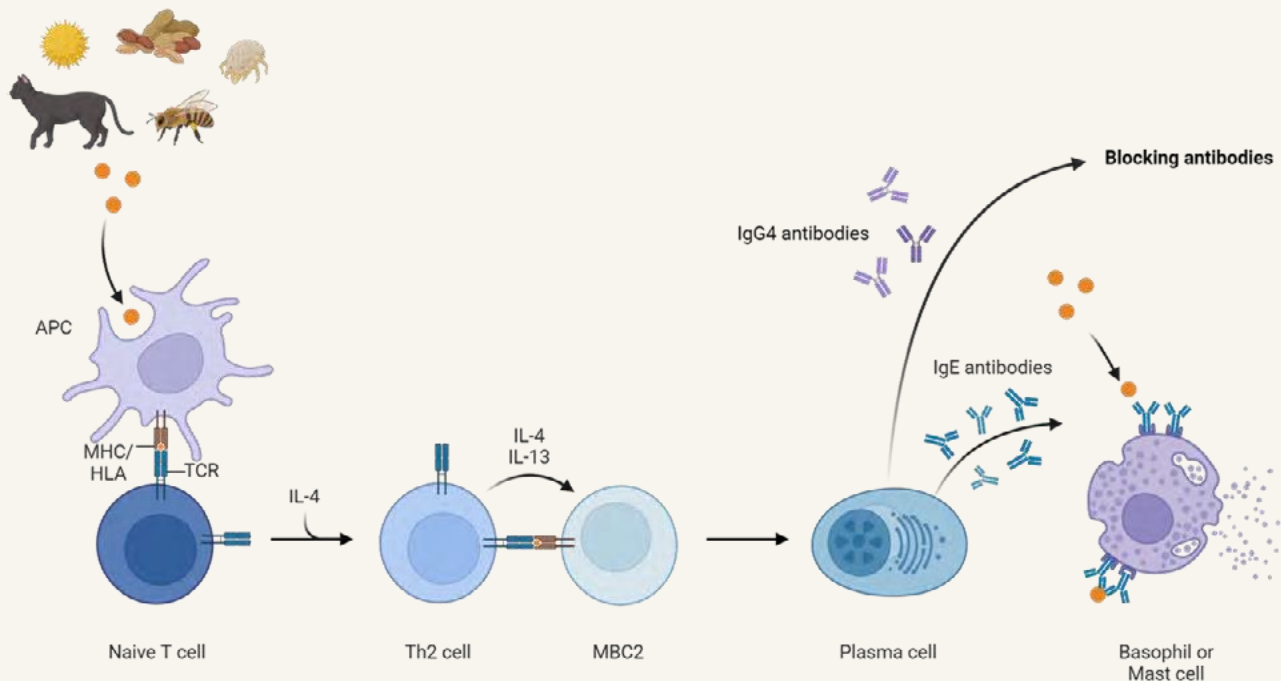
- Internationally recognised centre in AIT mode of action
- World leading centre in molecular and clinical allergology
- Expert knowledge in mast cell and basophil activation
- Expert knowledge in recombinant antibodies and lymphocyte biology



ALK well positioned to pursue new adjacent indications¹

Leveraging deep knowledge in "Type 2" immune mechanisms and dysregulation

Core pathways in the allergic inflammation



Allergy⁺

Examples of relevant adjacent indications¹

- Severe allergy
- Asthma
- Atopic dermatitis
- Mast cell disease, e.g.
 - Urticaria
 - Mastocytosis

Closing remarks

- Our R&D vision entails increased investments towards building a balanced pipeline for greater, long-term growth
- Strengthen leadership in respiratory allergy, and build a global position in anaphylaxis
- Pursue a portfolio strategy in food allergy with the Peanut tablet as point of entry
- Build upon a foundation of innovative research to expand into new adjacent indications
- Ample opportunities to leverage core R&D capabilities and scientific leadership to amplify innovation and serve more patients with allergy