



# Q1 2013 & full-year outlook

Presentation 3 May 2013



3 May 2013

# Today's agenda

## Q1 PRESENTATION

- Highlights
- Revenue trends and results
- Pipeline update
- 2013 outlook
- Q&A session



CEO Jens Bager

CFO Flemming Pedersen

## HDM AIT PRESENTATION

- House dust mite allergy
- Patient dynamics in Europe
- MITRA and MERIT
- Q&A session



EVP, Head of R&D Henrik Jacobi

# Highlights in the quarter

## Milestones in globalisation of tablet vaccines

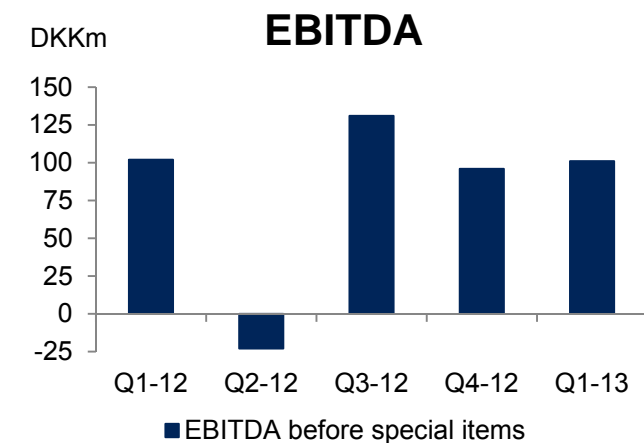
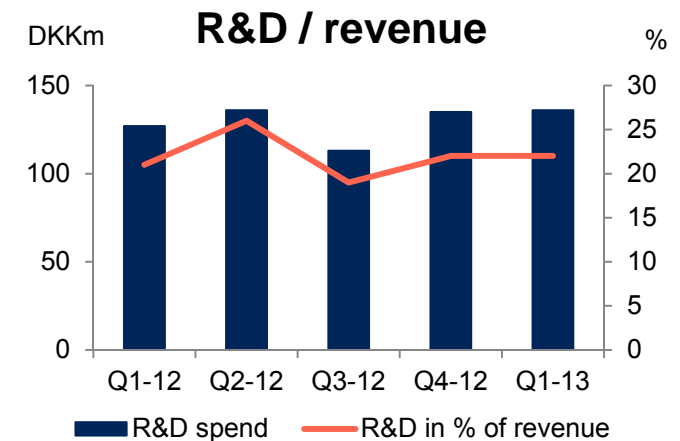
- FDA accepted the BLA for grass AIT for review (March)
- Ragweed AIT filed in the USA (March) and Canada (April)
- ALK presents HDM AIT Phase III results during Q3

## Q1 operating profit better than anticipated

- DKK 101m EBITDA (102) despite increased R&D efforts
- Cost reductions and efficiency improvements

## Full-year outlook maintained

- Revenue >DKK 2.3bn; DKK 200-300m EBITDA



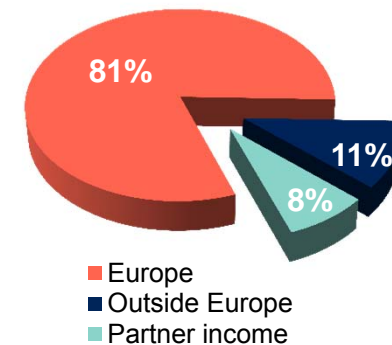
# Market update

## Europe

- Slight decline in vaccine sales in weaker markets, except for France, Nordic and Eastern/Central Europe
- New austerity measures in the Netherlands
- ALK maintains its overall market shares
- Continued strong market uptake of Jext<sup>®</sup>



## Group revenue



## Outside Europe

- Commodity sale ceased
- China: double-digit growth in vaccine sales
- North America: 3% growth in sales of extracts



## Partner income

- USD 5m milestone payment from Merck related to ragweed AIT
- Reimbursement of R&D activities carried out for Merck and Torii



# Product sales

## SCIT & SLIT vaccines

-4%

- Depressed sales in Central and Southern Europe
- SCIT growth in Nordic, France and overseas

## Tablet vaccines (AIT)

+6%

- 6% sales growth
- 11% volume growth
- Strong growth in France, Central/Eastern Europe

## Adrenaline

+92%

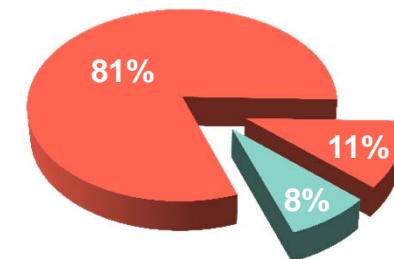
- Growth driven by UK, Nordic and France
- Market share now estimated at >10%
- Sales target: DKK 200m

## Other products

-17%

- Decline in diagnostics
- Double-digit growth in PRE-PEN<sup>®</sup> sales
- Discontinuation of commodity sales

Product sales



- SCIT & SLIT vaccines
- Tablet vaccines
- Adrenaline and Other products



# Quarterly results

DKK million	Q1-2012	EURm	Q1-2013
Revenue	607	82	<b>610</b>
Gross profit	445	60	<b>446</b>
Capacity costs	374	50	<b>376</b>
EBITDA before special items	102	14	<b>101</b>
EBITDA	102	14	<b>101</b>
Net result	40	6	<b>42</b>

DKK million	Q1-2012	EURm	Q1-2013
Operations	45	11	<b>82</b>
Investments	(50)	(8)	<b>(56)</b>
Financing	(30)	(8)	<b>(57)</b>

Unchanged gross margin of 73%

R&D expenses up 7%

Admin. expenses declined 6%

Sales/marketing expenses declined 2%

Dividends and share buy-backs

# Forward-looking statements

This presentation contains forward-looking statements, including forecasts of future revenue and operating profit as well as expected business-related events. Such statements are naturally subject to risks and uncertainties as various factors, some of which are beyond the control of ALK, may cause actual results and performance to differ materially from the forecasts made in this presentation. Without being exhaustive, such factors include e.g. general economic and business-related conditions, including legal issues, uncertainty relating to demand, pricing, reimbursement rules, partners' plans and forecasts, fluctuations in exchange rates, reliance on suppliers and market structure. An additional factor is potential side effects from the use of ALK's existing and future products as allergy immunotherapy may be associated with allergic reactions of differing extent, duration and severity.

# Financial outlook 2013

## Revenue on par with 2012

- Stable vaccine sales
- Solid growth in Jext<sup>®</sup> sales
- Minor growth in diagnostics and other products
- Lower income from partners (milestones, etc.)

## Unchanged capacity costs

- R&D expenses > DKK 500m

## Robust DKK 200-300m operating profit

- Subject to timing of milestone payment from Merck
- Earnings mainly to be generated in Q4

### 2013 Outlook (DKK)

Revenue	>2.3bn
Operating profit (EBITDA)*	200-300m
CAPEX	200-250m

\*) before special items



# Tablet development on track

Product	Geography	Pre-clinical	Phase I	Phase II	Phase III	Filing (exp.)	Marketed
GRAZAX® Grass ARC*	Europe	█	█	█	█	█	█
Grass AIT** Grass ARC	North America	█	█	█	█	█	█
GRAZAX® Asthma prevention	Europe	█	█	█	█	(2016)	
Ragweed AIT Ragweed ARC	North America	█	█	█	█	█	█
HDM*** AIT HDM asthma	Europe	█	█	█	█	(2014)	
HDM AIT HDM rhinitis	Europe	█	█	█	█	(2014)	
HDM AIT HDM rhinitis	North America	█	█	█	█	(n.d.)	
HDM AIT HDM asthma	Japan	█	█	█	█	(n.d.)	
HDM AIT HDM rhinitis	Japan	█	█	█	█	(n.d.)	
Tree AIT Tree ARC	Europe	█	█	█	█	(n.d.)	

- Results from MERIT and MITRA Phase III trials expected during Q3
- Results from Tree AIT Phase II in H2 and HDM AIT Phase IIb, USA ~Q4



# Q&A Session



# Tablet development on track

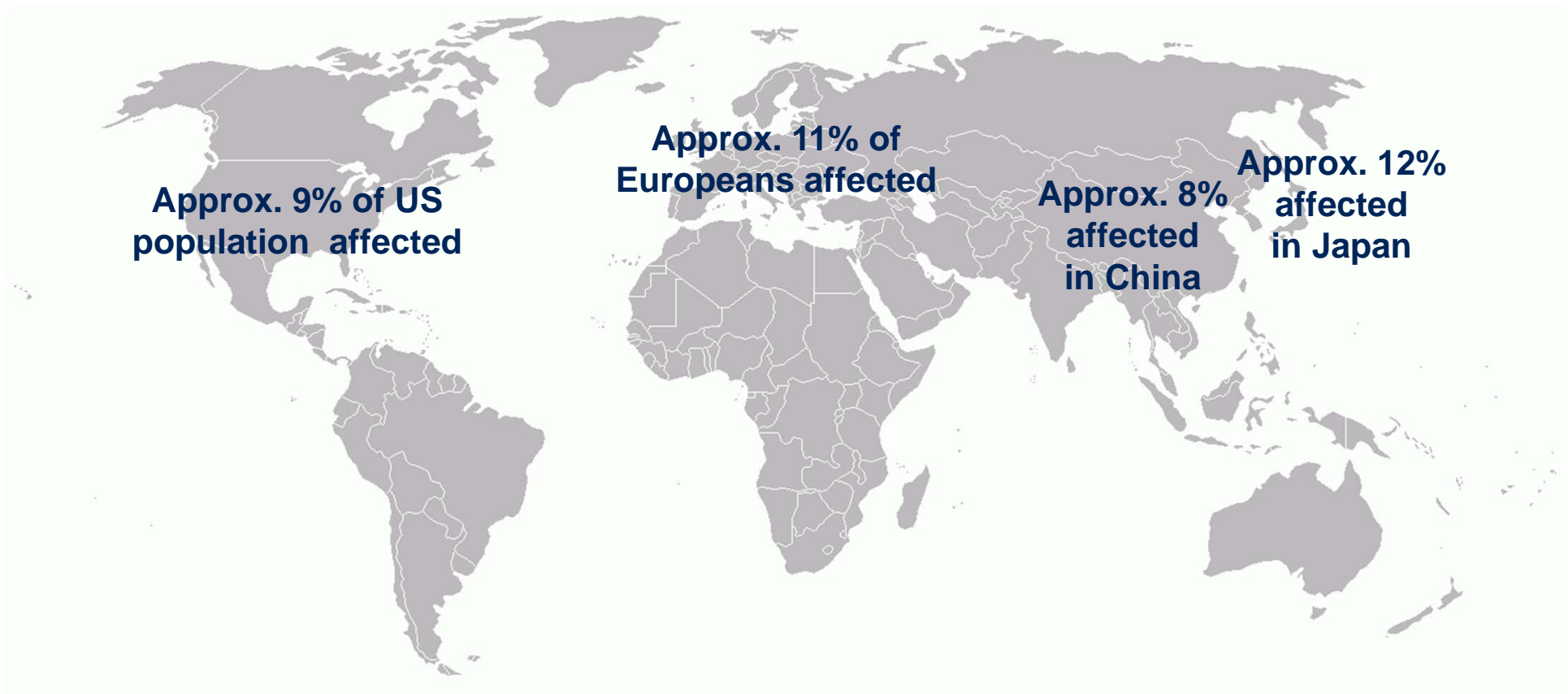
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HDM AIT HDM asthma	Japan	█	█	█	█	(n.d.)	
HDM AIT HDM rhinitis	Japan	█	█	█	█	(n.d.)	
Tree AIT Tree ARC	Europe	█	█	█	█	(n.d.)	

- Results from MERIT and MITRA Phase III trials expected during Q3



# House dust mite (HDM) allergy

The world's most prevalent allergy



**200 million people affected in the USA, Europe, China & Japan**

# HDM allergy

Perennial allergy with strong link to asthma

## Clinical symptoms of rhinitis and asthma

- 50% of HDM allergic rhinitis patients suffer from allergic asthma
- Most HDM allergic asthma patients also have allergic rhinitis

## Early onset and occurrence in life

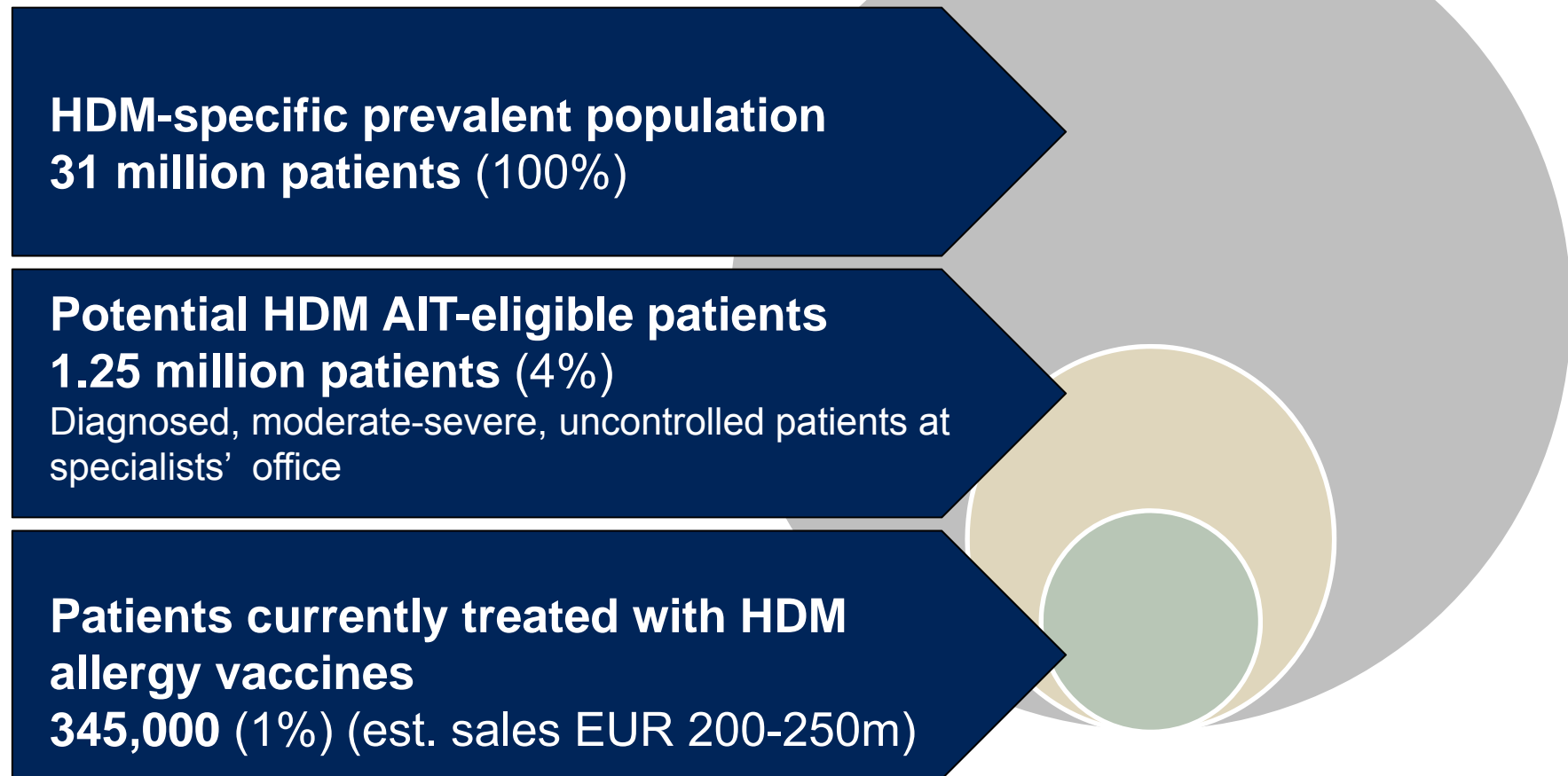
### UK birth cohort trial\*

- 13% sensitised to HDM at age four years
- 8x higher risk of developing asthma if sensitised to HDM



# Patients in EU top 5 markets

A large population is currently not treated with allergy vaccination



# Tablet development on track

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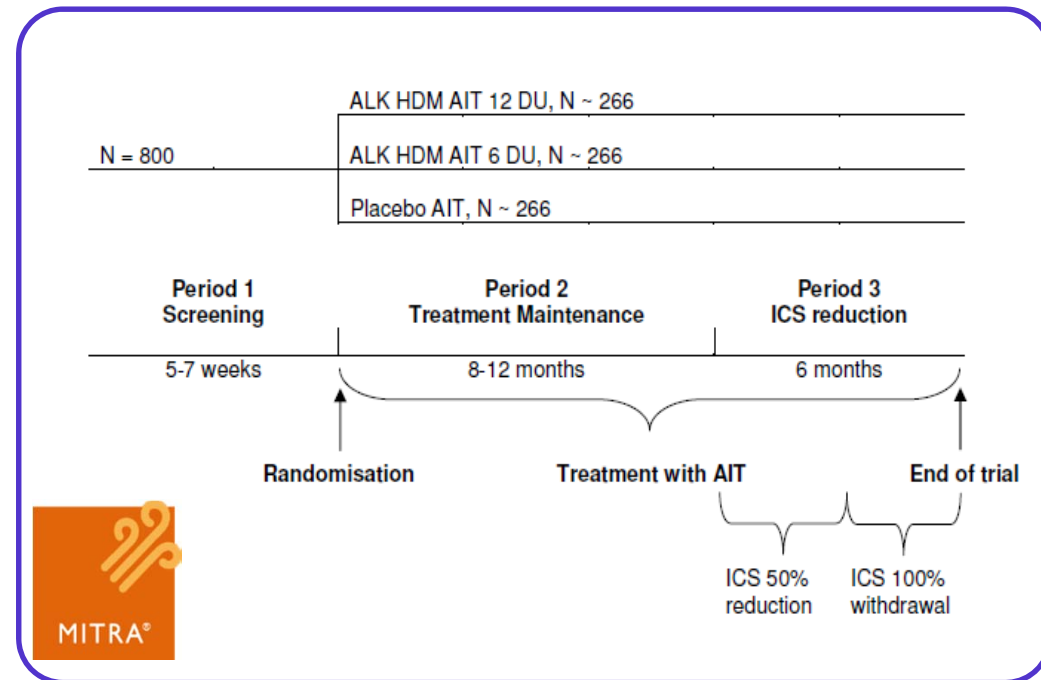
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# MITRA trial

Establishing efficacy in the treatment of HDM-related allergic asthma

- Treatment of house dust mite-allergic patients with asthma
- Primary endpoint: reduction of asthma exacerbations



# MITRA study design

## Building a case for HDM AIT in HDM-induced allergic asthma

### Primary Objective

- Evaluate the efficacy of once daily HDM tablets (6 DU and 12 DU) compared to placebo in subjects with HDM-induced asthma, measured by reduction of risk for an asthma exacerbation

### Key Secondary Objectives

- Determine the effects on asthma symptoms and immunology

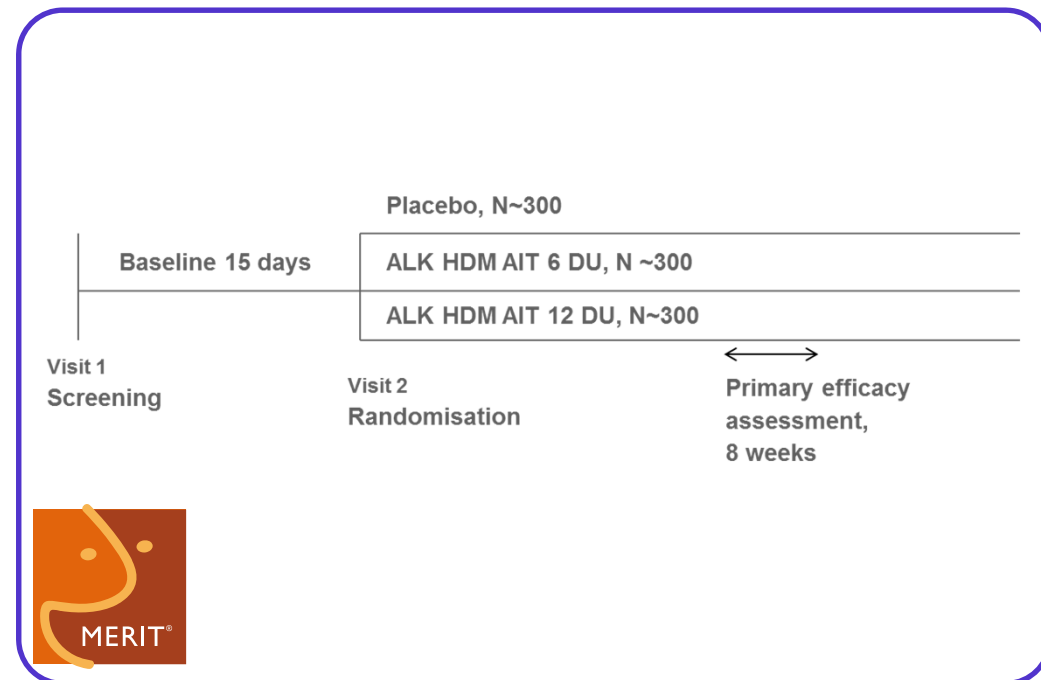
### Other Secondary Objectives

- Effects on lung function, asthma control, safety, symptomatic medication, asthma quality of life and pharmaco-economics

# MERIT trial

Establishing efficacy in the treatment of HDM-related allergic rhinitis

- Treatment of house dust mite-allergic patients with rhinitis
- Primary endpoint is reduction in average total combined rhinitis score



# MERIT study design

## Building a case for HDM AIT in HDM-induced allergic rhinitis

### Primary Objective

- Evaluate the efficacy of once daily HDM AIT compared to placebo in the treatment of HDM allergic rhinitis.
- Primary endpoint: average total combined rhinitis score during the last eight weeks of treatment

### Key Secondary Objectives

- Determine the effects on average allergic rhinitis DSS, average allergic rhinitis DMS and average total combined rhinoconjunctivitis score

### Other Secondary Objectives

- Evaluate the safety and tolerability of HDM AIT
- Effects on individual rhinitis and conjunctivitis symptoms, medication use, onset of action, treatment satisfaction, and generic and disease-specific quality of life
- Immunological parameters will be investigated in a subset of subjects

# An unprecedented clinical development programme

	Phase	Region	Age	N	Main aim
<b>Completed trials</b>					
<b>MT-01</b>	I	Europe	18-65	71	Tolerability and safety
<b>MT-02</b>	II/III	Europe	14-74	604	Dose-finding and efficacy on asthma
<b>MT-03</b>	I	Europe	5-14	72	Tolerability and safety
<b>TO-203 Phase I</b>	I	Japan	21-49	48	Tolerability and safety
<b>Ongoing trials</b>					
<b>MT-04 (MITRA)</b>	III	Europe	≥18	834	Efficacy in asthma
<b>MT-06 (MERIT)</b>	III	Europe	≥18	900	Efficacy in rhinitis
<b>TO-203-3-1</b>	II/III	Japan	18-50	900*	Efficacy in asthma
<b>TO-203-3-2</b>	II/III	Japan	12-50	900*	Efficacy in rhinitis
<b>MK-8237-008-00</b>	I	North America	12-17	195**	Tolerability and safety
<b>MK-8237-003-01</b>	IIb	Europe	≥18	100**	Dose-finding (exposure chamber trial)
<b>MK-8237-001-00</b>	III	North America	≥12	1500**	Efficacy in rhinitis/rhinoconjunctivitis

\*) In partnership with Torii

\*\*\*) In partnership with Merck

# The house dust mite allergy tablet

A key step in ALK's growth plans

## Effectively treat the most important global allergy

- Drive global expansion (established and emerging markets)
- Expand the AIT portfolio

## The long-term vision for HDM AIT

- Treatment of house dust mite induced respiratory disease (rhinitis and asthma)
- Disease modification in adults and children
- Prevention of asthma in children



# Thank you for your attention

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