

# A world leader in allergy immunotherapy

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Global Healthcare Conference

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Jens Bager, President & CEO

Becoming a global  
specialty pharma company



# ALK at a glance

Leading allergy immunotherapy (AIT) specialist

AIT: Treats the root cause of allergy

- ALK has 33% of the global AIT market
- 1.5 million patients using ALK products
- 1,800 employees, ~350 in R&D
- SLIT-tablets: >10 years of R&D investment and clinical trials in ~ 15,000 patients
- Next R&D frontier: asthma treatment & prevention

Products in all areas of AIT



Sublingual tablets (SLIT-tablets)



Sublingual drops (SLIT-drops)



Other, including diagnostics, adrenaline and anti-venom



Subcutaneous (SCIT) or allergy shots

# A strong foundation for future growth

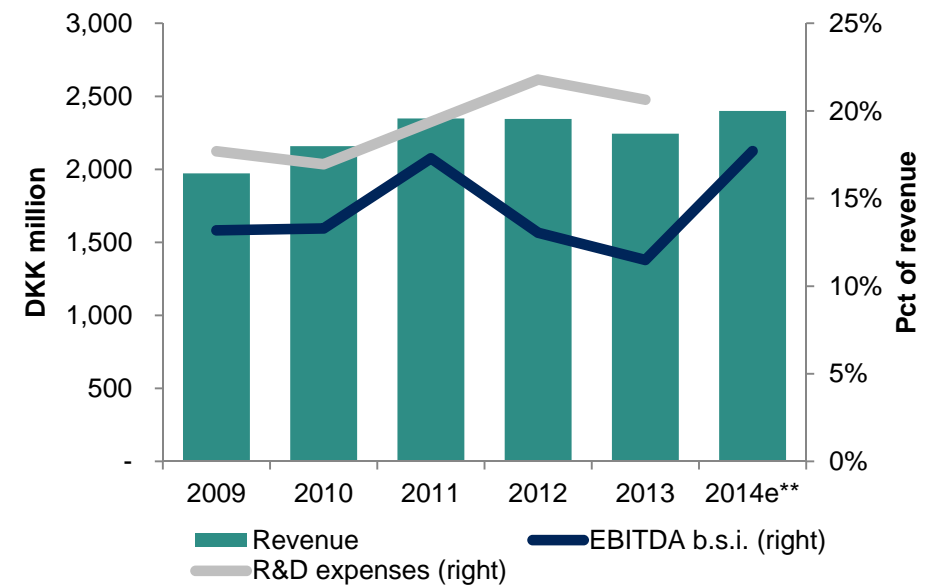
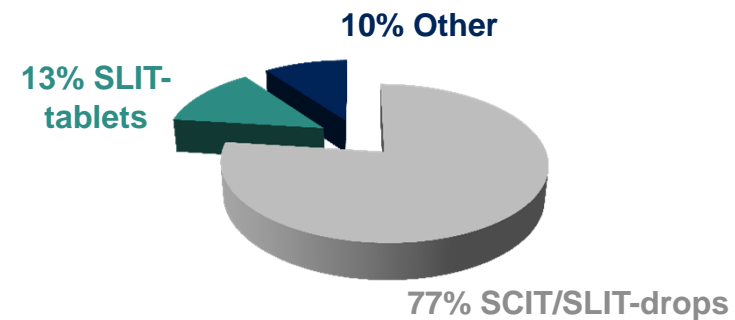
Positive free cash flow expected in 2014

## 2013 financial highlights

- Revenue: DKK 2.2bn (USD 400m)
- R&D expenses: DKK 416m
- EBITDA (b.s.i.\*): DKK 258m (USD 46m)
- CAPEX: DKK 209m
- Equity ratio: 69%
- Dividend: DKK 5 per share

## Shareholder info

- Listed on NASDAQ OMX Copenhagen
  - : (Reuters: ALKB.CO / Bloomberg: ALKB.DC)
- Market cap. ~EUR 1.1bn
- Main shareholder: Lundbeck Foundation



\* Before special items

\*\*Before future income streams from product supply and sales royalties from SLIT-tablets in North America

# Growth through global commercialisation

Partnerships to leverage growth



**ALK North America**  
Own sales and distribution in the USA and Canada

**Merck partnership**  
Exclusive rights to develop and commercialise SLIT-tablets in the USA, Canada and Mexico

**USD 290 million** in milestones. Revenue from royalties and product supply

**North America**  
16% of revenue

**ALK Europe**  
Own sales and distribution in 16 European countries

High quality Product Supply organisation with global capacity

**Europe**  
81% of revenue

**Torii partnership**  
Exclusive rights to develop and commercialise SLIT-tablets in Japan  
**EUR 60+ million** in milestones. Revenue from royalties and product supply

**Eddingpharm collaboration**  
Sales and distribution of marketed products in China

**Abbott partnership**  
Supply and marketing of SLIT-tablet portfolio in selected emerging markets

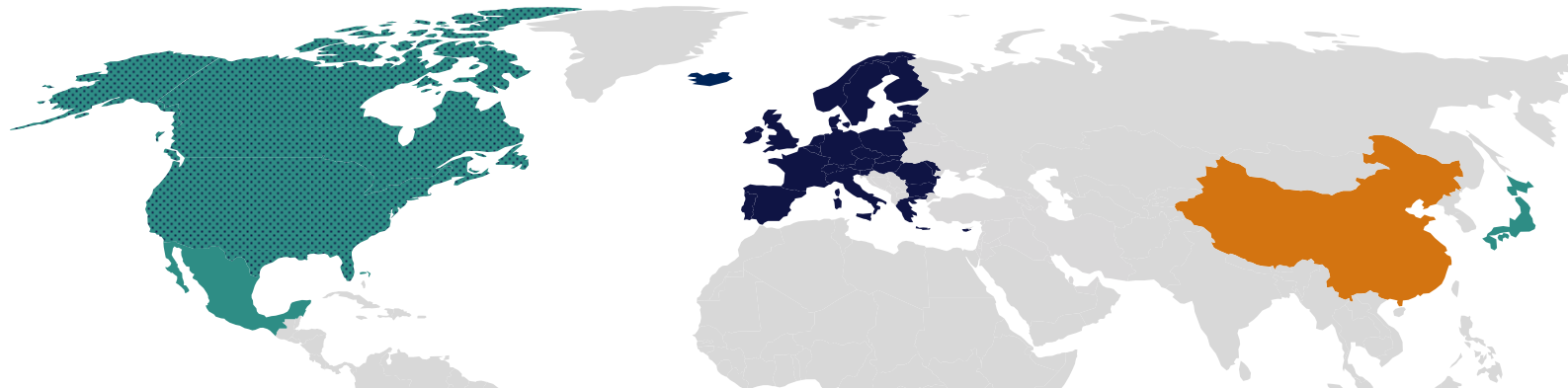
**International**  
3% of revenue

# Allergy: A chronic global disease

400-500 million affected worldwide, 10-20% severely

- Allergy: an overreaction to substances that are usually harmless
- Respiratory allergies include allergic rhinoconjunctivitis (AR) and allergic asthma
- AR affects the upper airways, nose and eyes
- 30-60% of AR patients develop allergic asthma

## Unmet need for severely affected patients



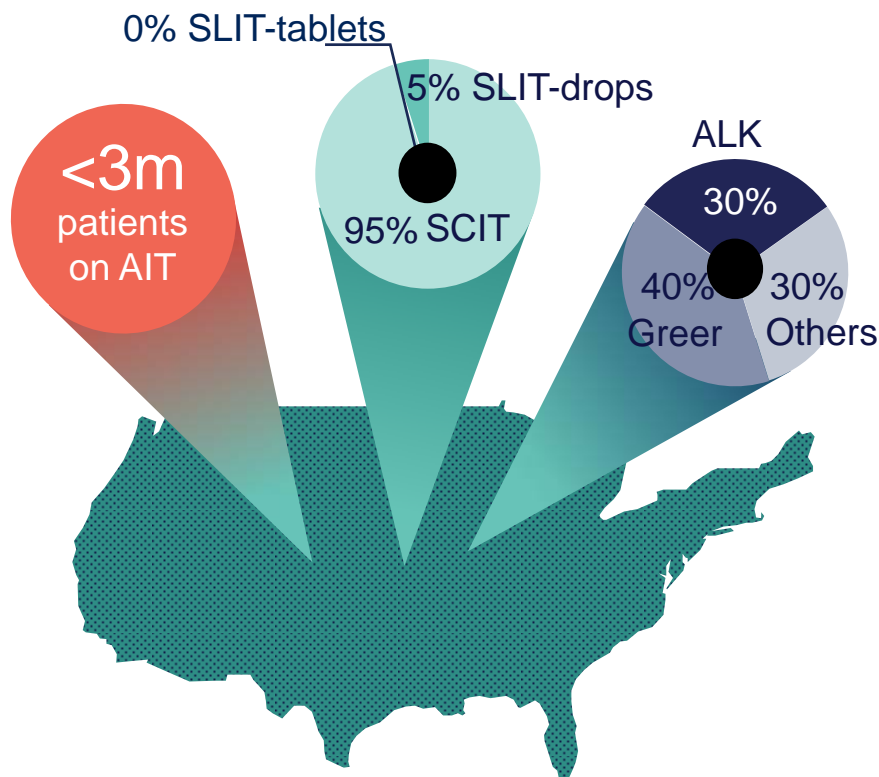
	North America	Europe	China	Japan
Key allergens	HDM, Grass, Ragweed, Tree	HDM, Grass, Tree	HDM	HDM, Japanese cedar
Severe AR cases*	<b>6-12m</b>	<b>11-22m</b>	<b>19-38m</b>	<b>5-10m</b>

# United States: The next opportunity

High allergy prevalence, take-up of AIT affected by inconvenience

Billing: \$2-3bn, industry revenue: \$120m

USA: Market profile



- Dominated by SCIT, with self-mixing and compounding by allergists common
- 5,500 AIT practitioners; increasing interest from ENTs and others
- >6 million severe patients eligible for AIT
- SCIT: low take-up and high drop-out rate
  - 50% refuse treatment, 84% drop out
- SLIT-tablets are the first FDA-approved AIT treatments (approved in 2014)
- Major unmet need in AR, claiming:

**3.5m**  
lost work days

**2m**  
lost school days

**\$14bn**  
in direct costs

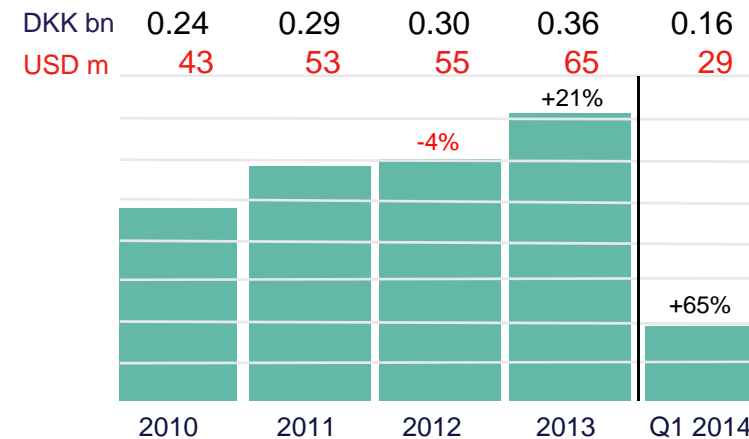
# United States: Parallel growth strategy

Merck partnership co-exists with ALK's allergen extracts business

## USA: ALK's strategy

- Merck
  - Partnership for grass, ragweed and HDM SLIT-tablets
  - GRASTEK<sup>®</sup> and RAGWITEK<sup>™</sup> approved and launched in 2014, HDM tablet in Phase III
  - List price: USD 8.25 per tablet
- ALK North America
  - Allergen extracts and other products delivered to allergists

## North America: Revenue

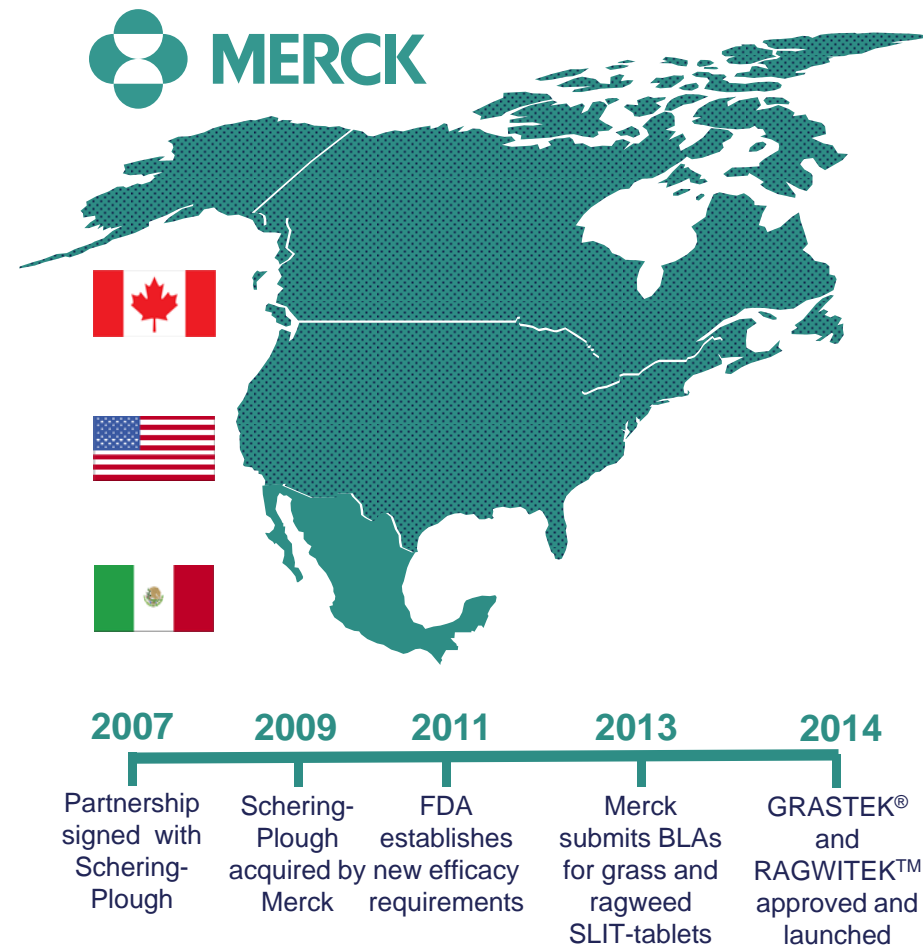


# Merck partnership for North America

Co-exists with ALK's allergen extracts business

## Terms of the partnership

- Develop, register and commercialise SLIT-tablets in USA, Canada and Mexico
- Covers grass, ragweed and house dust mite
- Up to DKK 1.6 billion (USD 290 million) in milestone payments
  - US\$ 100 upfront and in milestones
  - ~ US\$ 85 million paid 2007-2014
  - US\$ 190 in sales milestones
- Revenue from royalties and product supply

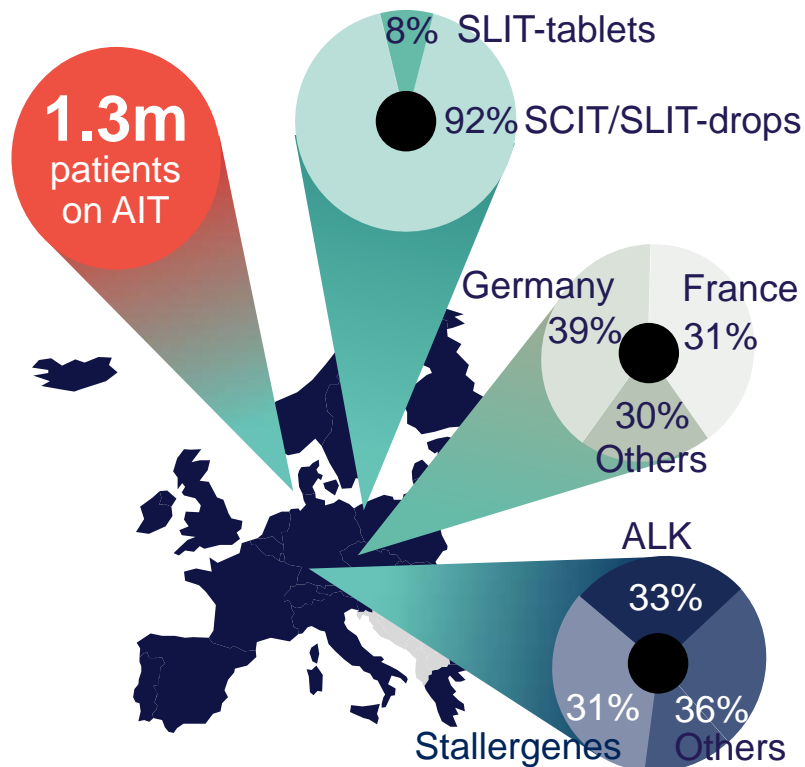


# Europe: A market in transition

ALK's core platform

Total industry sales: ~EUR700m

Europe: Market profile



- Mature, diverse markets
- Legacy and named patient products
- Restricted market access
- Uneven prescriber coverage
- Under regulatory transformation
- SLIT-tablets fully-documented and registered



# Europe: Meeting the challenge of change

Increased efficiency, focused investments and market shaping activities

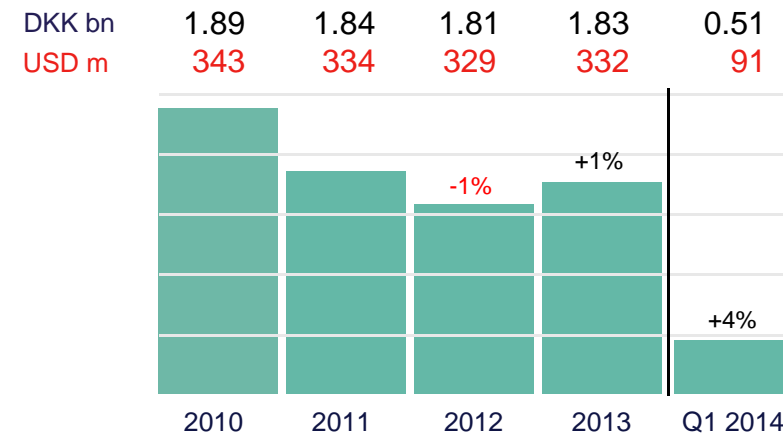
## Europe: ALK's strategy

- Medium-term growth prognosis: 0-5% pa
- Activities to gain market share
- New product launches
- Improve earnings through cost efficiencies

### 'Allergy Unlocked'

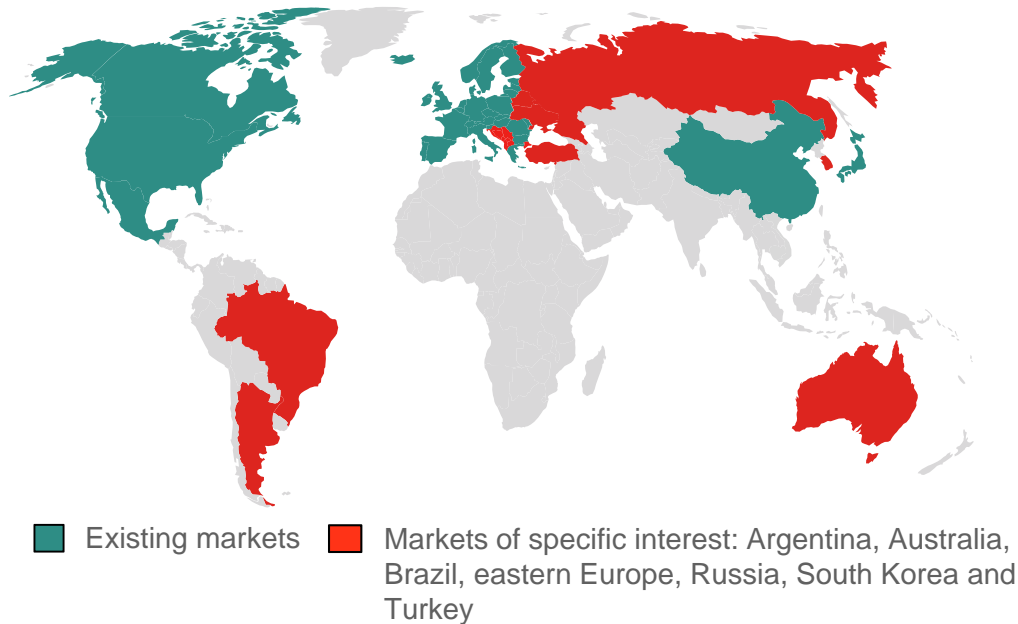
Raise awareness of disease burden  
 Secure scientific support  
 Improve market access  
 Increase patient awareness  
 Expand prescriber base

## Europe: Revenue

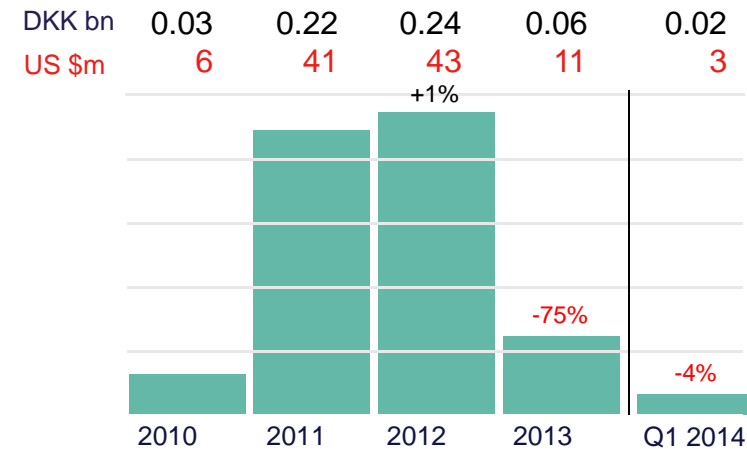


# Globalising a proven portfolio

Expanding beyond established AIT markets



## International: Revenue



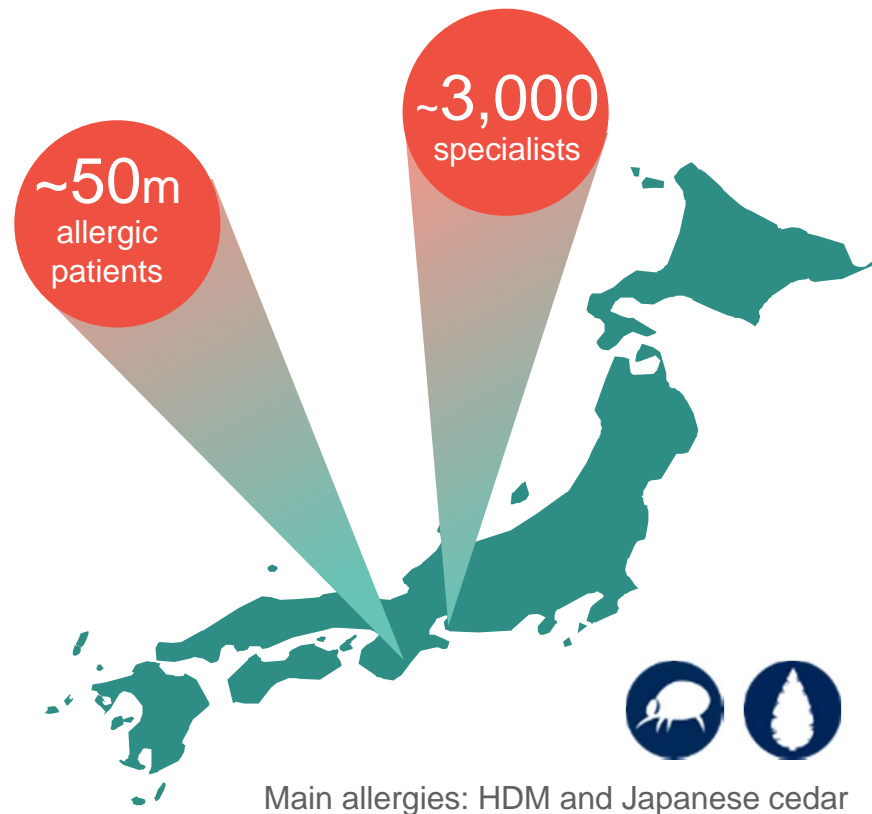
## International markets:

- Torii partnership in Japan for HDM and Japanese cedar SLIT-tablets
- Abbott: Supply and marketing of SLIT-tablet portfolio in selected emerging markets
- Eddingpharm in China: Sales and distribution of marketed products

# Japan: A new opportunity

Addressing the national affliction

Emerging AIT market



Japan: Market profile

- Allergy prevalence higher than EU and USA
- AIT currently almost non-existent as a treatment option

Japan: ALK's strategy

- Partnership with Torii for HDM and Japanese cedar SLIT-tablets
- Positive Phase III trial results from HDM tablet in March 2014
- On-going Phase III trial in to allergic asthma
- Phase II/III trial with Cedar tablet to be initiated in H2 2014
- SCIT HDM licensed for market-building

# SLIT-tablet pipeline: Covering major allergies

Clinical data from 36 trials in >15,000 patients

	Product	Pre-clinical	Phase I	Phase II	Phase III	Filing (exp.)	Marketed
	GRAZAX® Grass ARC	█	█	█	█		2007
	GRAZAX® Asthma prevention	█	█	█	█	2016	
	HDM SLIT-tablet HDM asthma	█	█	█	█	2014	
	HDM SLIT-tablet HDM rhinitis	█	█	█	█	2014	
	Tree SLIT-tablet Tree ARC	█	█	█	█	TBC	
	GRASTEK®* Grass ARC	█	█	█	█		2014
	RAGWITEK™* Ragweed ARC	█	█	█	█		2014
	HDM SLIT-tablet* HDM rhinitis	█	█	█	█	TBC	
	HDM SLIT-tablet** HDM rhinitis	█	█	█	█	TBC	
	HDM SLIT-tablet** HDM asthma	█	█	█	█	TBC	
	Japanese cedar SLIT-tablet Cedar tree ARC	█	█	█	█	TBC	

ARC: allergic rhinoconjunctivitis  
HDM: house dust mites

\*) Licensed to Merck for North America  
) Licensed to Torii for Japan

# GAP trial: GRAZAX Asthma Prevention

Preventing the progression of allergic disease

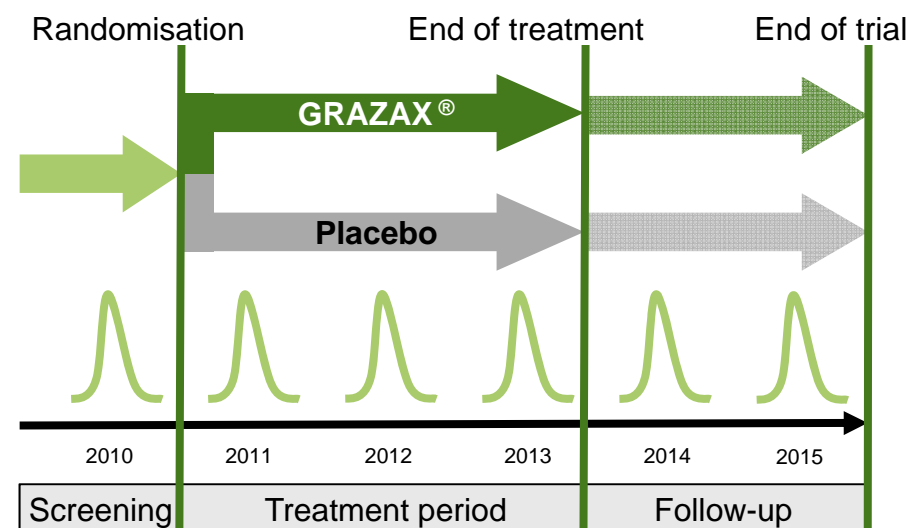
## Asthma prevention trial

- Initiated in 2010, completes in 2015
- Assesses effect of GRAZAX<sup>®</sup> on risk of developing asthma compared to placebo
- Potential new offering in the use of allergy immunotherapy

## Pan-European paediatric trial

- Multi-national, multi-centre trial: 101 sites in 11 European countries
- Patients: 812 children aged 5-12 with grass allergy but no asthma

## Trial design

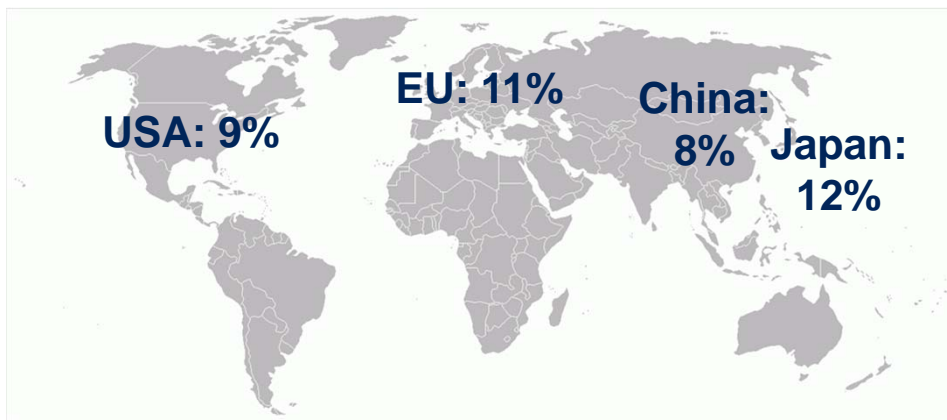


# SLIT-tablet for the most common allergy

200 million allergic to house dust mites in Europe, USA, Japan and China

## HDM allergic disease

- Perennial disease; strong link to asthma
- Most common allergy: 200 million affected in Europe, the USA and China



HDM allergy affects around 10% of the population

## Development status: HDM SLIT-tablet

- Global development programme in 6,000 patients
- Best in class documentation
- In 2013, MERIT & MITRA Phase III trials both met primary endpoints
- In 2014: Japanese Phase III rhinitis efficacy trial met primary endpoint
- Japan: Ongoing Phase III trial for efficacy in asthma
- USA: Merck completed Phase IIb trial; Phase III trial initiated in Q1 2014



# From strategic vision to commercial returns

Major developments ahead



- Driving for profitability in Europe
- Realising the opportunity in North America
- Seizing the unfolding opportunity in Japan
- HDM SLIT-tablet in final stages of clinical development
  - A global product for a worldwide allergy
- Enhancing ALK's position in China
- Expanding into emerging markets
- Exploring the potential of AIT in allergic asthma and asthma prevention

# Thank you for your attention

Read more: [www.alk.net](http://www.alk.net)

Investor Relations:

Per Plotnikof

Head of Investor Relations

Phone: +45 4574 7576

E-mail: [ppidk@alk.net](mailto:ppidk@alk.net)

