

# Delivering on our strategy

**Preliminary Results for the year end 30 June  
2018**

**Manuel Llobet, Chief Executive Officer**  
**Nick Wykeman, Chief Financial Officer**



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# 2018 highlights

PQ Grass 

## Phase II success

*Progression to Phase III in US in 2019*

PQ Birch

## Phase III finished

*Top line readout before end of 2018*

Increase in market share over 12 months to June 2018

## 1 point increase in market share

**6.6%\*** increase in *reported revenue* to **£68.3m** (2017 £64.1m)

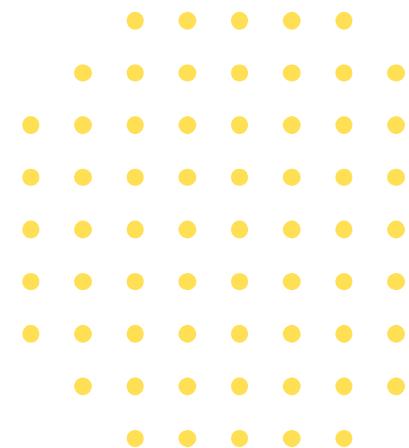
**26%** increase in operating profit pre R&D\*\*

Oversubscribed fundraising of **£10.6m** gross

Cash balance of **£15.5m** (2017: £22.1m)

\*3.5% increase at constant currency rate (2018 £66.369m, 2017:£64.139m). Constant currency uses prior year weighted average exchange rates to translate current year foreign currency denominated revenue to give a year on year comparison excluding the effects of foreign exchange movements.

\*\*Operating Profit (pre R&D) is calculated by adding back R&D expenditure for the year to the operating loss of the year to arrive at operating profit (pre R&D) of £9.3m (2017: £7.4m)



# Our Business and Strategy

# Three Pillars to Growth: Advancing a Leading Allergy Immunotherapy Company

## Three pillars to the business

01

### Expanding in Europe

Strongly performing profitable business

Growing market share and additional product registrations



02

### Strong pipeline

New technologies underpin pipeline breadth and depth

Investment strategy supported by growing revenue stream



03

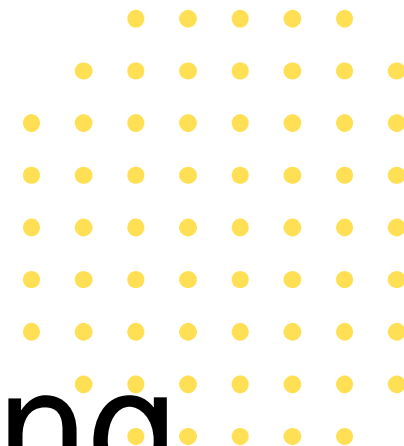
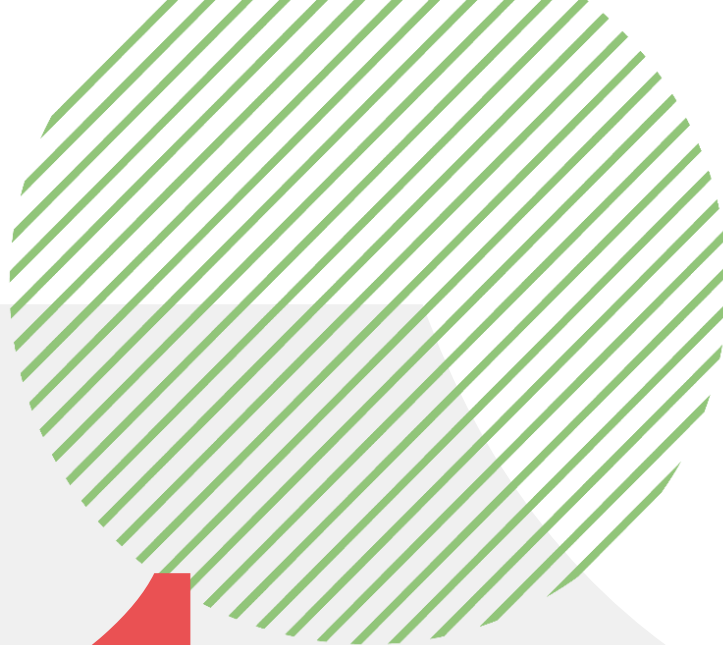
### Preparing for US entry

Significant opportunity in largest allergy market

Changing regulatory and reimbursement environment to drive market share towards Allergy's products



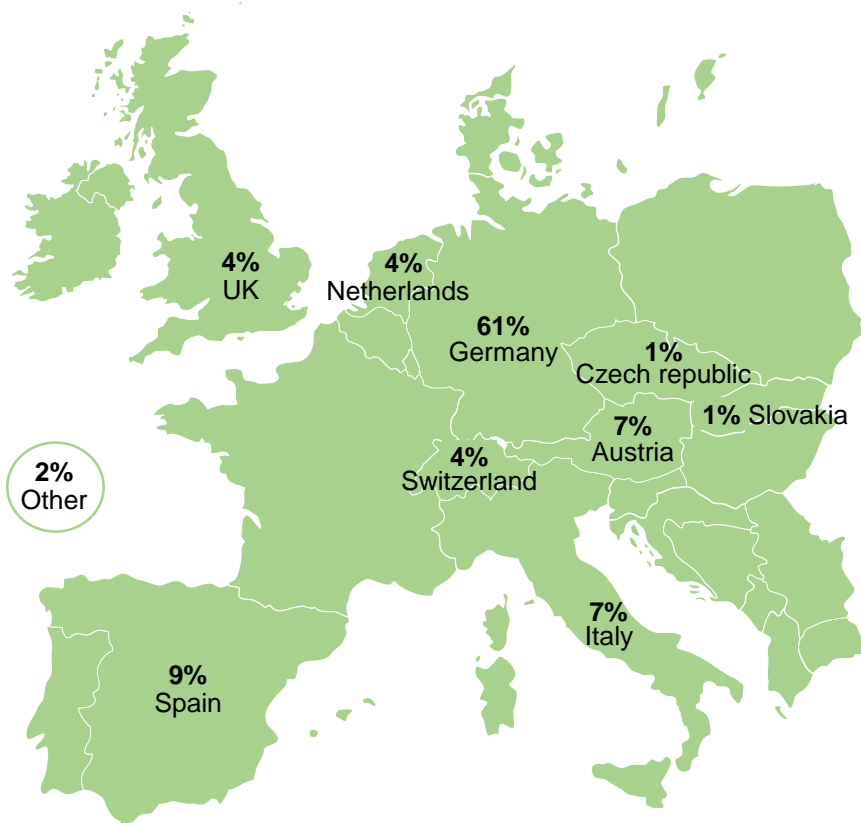
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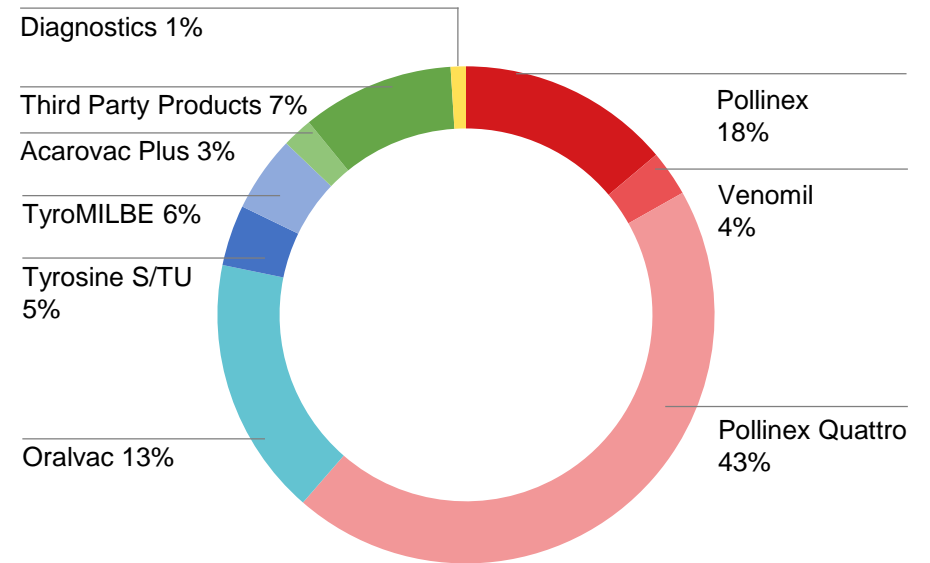
# Expanding in Europe

# Sales breakdown for FY 2018

## Sales by country



## Sales by product<sup>1\*</sup>



Pollinex Quattro

Pollinex

Tyrosine

Oralvac

<sup>1</sup> Sales breakdown based on gross sales at budget exchange rates (before freight, rebates and exchange) : £66.0 million.

After deducting rebates, freight charges and foreign exchange adjustments, total sales for FY2018 is £68.3 million

**\*Allergy Therapeutics currently has no products licensed for sale in the USA**

# European business shows robust revenue stream

## Solid sales growth of 6.6%\* in 2018, increased market share by 1 point\*\* driven by:

Innovative, convenient and patient-friendly (short-course) products

Increased regulatory requirements to ATL advantage (TAV)

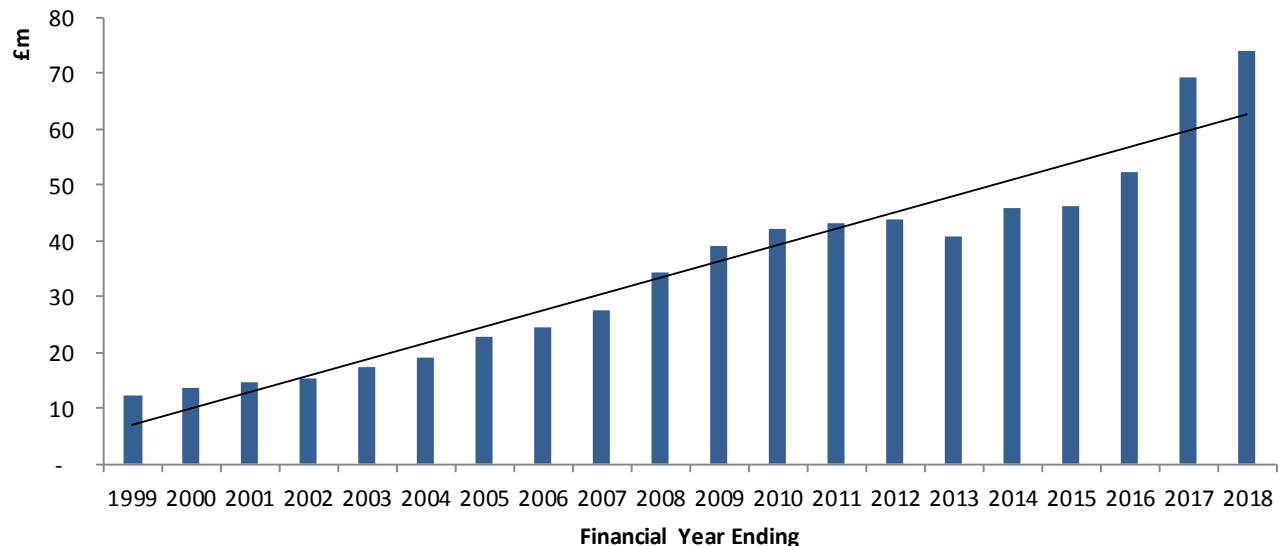
Focused investment across business reflected in performance

Strength of broad portfolio with modified Mite and Venom SCIT

Best in class commercial and sales teams

### 10% CAGR growth over last 19 years

\*3.5% increase at constant currency rate. (2018:£66.369m , 2017:£64.139m) Constant currency uses prior year weighted average exchange rates to translate current year foreign currency denominated revenue to give a year on year comparison excluding the effects of foreign exchange movements.



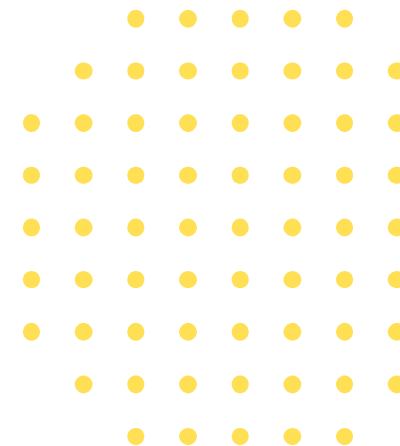
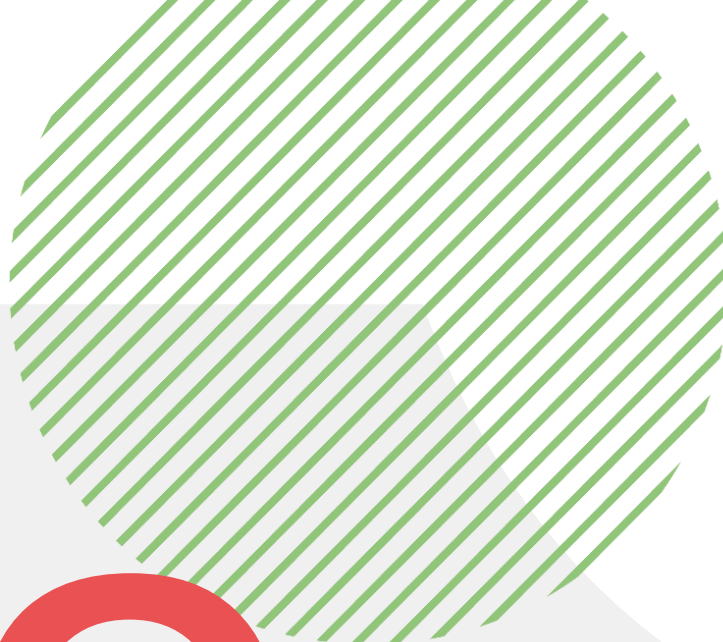
■ Gross Revenue (excludes rebates)

\*\*Market data and internal estimates for the year to 30 June 2018, for markets in which Allergy Therapeutics operates excluding Switzerland and UK (competitor data not available)


















02

Strong  
Pipeline



# Innovative, Broad Pipeline and Marketed Products

	Pre-clinical	Phase I	Phase II	Phase III	Market/Registered	Also available as a Named Patient Product	
Grass MATA		Short-course SCIT					
Tree MATA		Short-course SCIT					
Ragweed MATA		Short-course SCIT					
Bee Venom SCIT		Short-course SCIT					
Wasp Venom SCIT		Short-course SCIT					
Grass MATA MPL	 	Short-course Grass SCIT with MPL					
Birch MATA MPL		Short-course Birch SCIT with MPL					
Ragweed MATA MPL		Short-course Ragweed SCIT with MPL					
Trees MATA MPL		Short-course Tree SCIT with MPL					
Oral Grass, Trees & House Dust Mite	Sublingual immunotherapy with flexible-dosing						
Modified Mite Platform	Short-course modified Allergen HDM SCIT + MPL						
Peanut SCIT	Short-course Peanut SCIT						

# Key 2018 Trials

## PQ Birch

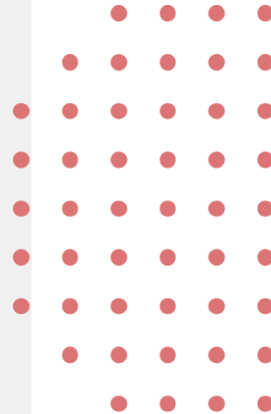


- Phase III field trial in Europe
- 582 patients from 59 centres in Germany, Austria, Poland and Sweden
- Double blind placebo controlled trial
- Pivotal trial for approval in Germany
- Combined Symptom Medication Score – based on patient daily symptom score and level of medication taken
- Co-seasonal trial
- Trial completed – read out before end of 2018

## PQ Grass

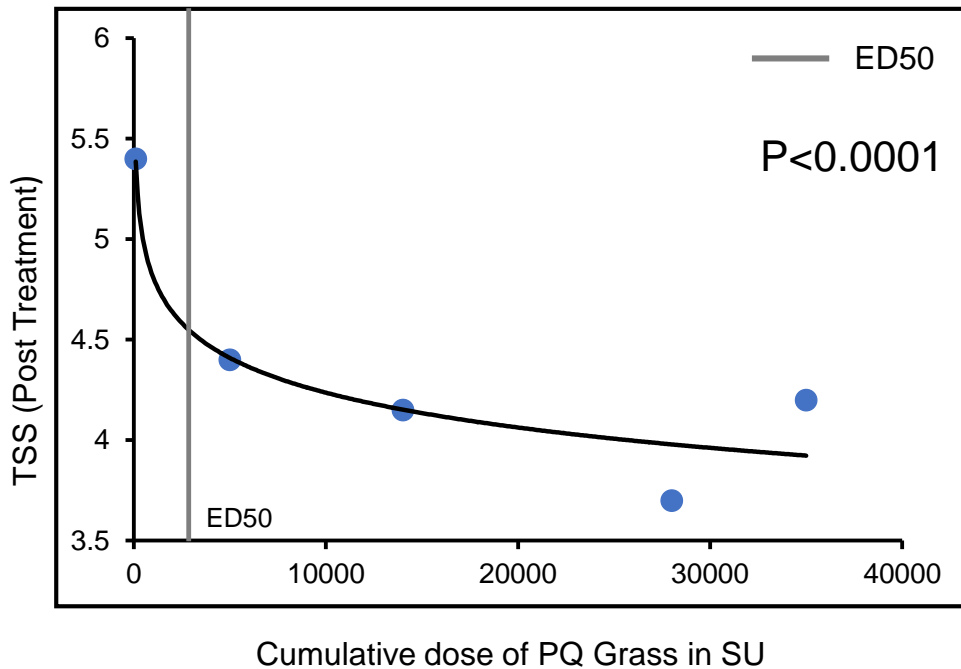


- Phase II dosing trial to move towards second Phase III trial + safety database
- Conjunctival Provocation Test to determine optimal efficacious cumulative dose
- 447 patients in 50 sites in Germany, Austria and Poland
- Total Symptom Score – measures four aspects of eye symptoms
- Pre-seasonal trial
- Highly positive results announced



# Optimal Grass Phase III dose identified: G205 Phase II Study

## Model Average



Significant  
reduction  
of symptoms with  
each  
dose relative to  
placebo

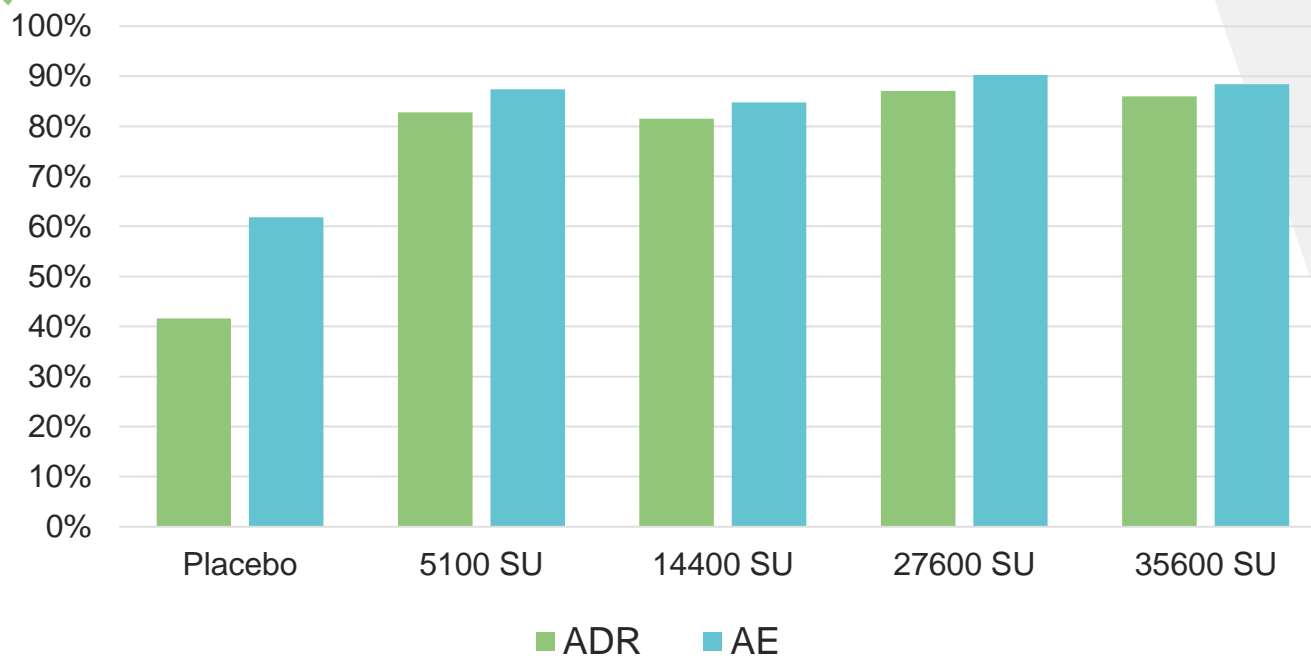
Treatment Group Estimated\* mean post – treatment Total Symptom Score (TSS) relative to Placebo

Significant increase  
in immunoglobulin  
results highly  
consistent with the  
dose response  
observed for the  
primary endpoint

## Model Averaging (mFAS)

\*Estimates from the model (curve fitting), not the descriptive point estimates  
ED50: The minimum dose that achieves 50% of the full effect size over Placebo

# Grass Phase II - Safety: Adverse Events / Adverse Drug reactions



No dose response in percentage of patients with adverse events or adverse drug reactions

G205 Grass Phase II  
—  
No SAEs

SAEs : Serious adverse event  
ADR: Adverse drug reaction  
AE: Adverse event

# Expected Grass MATA MPL Timelines



## Key Considerations for Grass MATA MPL

Market	<ul style="list-style-type: none"> <li>Allergies are the 6th leading cause of chronic illness in the U.S.<sup>1</sup> Market worth \$2bn/yr</li> <li>More than 50 million Americans suffer from allergies each year.</li> </ul>
Competition	<ul style="list-style-type: none"> <li>2<sup>nd</sup> Generation antihistamines (Claritin) started to become OTC in ~2003<sup>2</sup></li> <li>Allergra (Fexofenadine) and Xyzal (Levocetirizine) followed suit (OTC not covered by insurance)</li> <li>Grass tablet (Grastek) launched by ALK in 2014 (1 Grass spp. EpiPen co-prescribed)</li> <li>Grass tablet (Oralair) launched by Stallergenes in 2014 (5 Grass spp. EpiPen co-prescribed)</li> </ul>
Perception of Grass MATA MPL	<ul style="list-style-type: none"> <li>Modified allergen injected product (positive perception on enhanced safety profile)</li> <li>Inclusion of adjuvant MPL leads to shorter therapy duration &amp; thus increased compliance</li> <li>A registered injected AIT with proven efficacy would be beneficial (better than compounding)</li> </ul>
Pricing	<ul style="list-style-type: none"> <li>Grastek<sup>®</sup> costs \$300<sup>3</sup> and Oralair costs \$500<sup>4</sup> per 30 days</li> <li>Perception amongst HCPs in USA is that Grass MATA MPL should be ~\$2000<sup>5</sup></li> </ul>

<sup>1</sup> <https://www.cdc.gov/>

<sup>2</sup> <https://www.medicinenet.com/script/main/art.asp?articlekey=21882> (accessed Mar 2018)

<sup>3</sup> <http://www.rxeconsult.com/healthcare-articles/Grastek-Timothy-Grass-Pollen-Allergen-Extract-Cost-Dosage-Side-Effects-632/>

<sup>4</sup> <https://www.goodrx.com/oralair>

<sup>5</sup> Personal communication at AAAAI 2018

# Mite MPL house dust mite product

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**Phase I first patient treated**  
Study ongoing

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**Results of Phase I Trial**  
expected H1 2019

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**Acarovac product without**  
**MPL growing well in Spain**  
**and Austria**

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**Market opportunity of**  
\$3bn\* worldwide with only  
Europe partly tapped already

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**Potential of 8 injection**  
**model** compared to 12-15  
average of competitors and  
once a day for 3 years oral  
treatment

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**Potential additional product**  
**in US** portfolio following two  
Phase III trials

**Short-course**  
**product**  
**with global**  
**potential**

\*Datamonitor Epidemiology 2011

# Preclinical Pipeline: Polyvac peanut product

**Single dose of virus like particle (VLP)** combined with recombinant peanut allergen successfully **protects against anaphylaxis** when challenged with peanut

**Those vaccinated with candidate vaccine exhibited no symptoms** compared to placebo, when challenged with peanut

Safety profile of product evaluated and found **not to induce anaphylaxis**

**Manufacturing contract for scale-up of Polyvac product signed with AGC Biologics** with aim of having first trial in humans in 2019

**Peanut represents a new opportunity** into \$8bn\* worldwide food allergy market

**Pre-clinical development** progressing according to plan with important product differentiation demonstrated – aim is long-term immunity

**Positive results achieved from preclinical research of Polyvac Peanut**

\*The Journal of Allergy and Clinical Immunology 2016. 1% of US population. EACCI Food Allergy and Anaphylaxis Guidelines Group 2016 0.2% of Western European Population. Management assumption of annual treatment of \$2k





03

# Preparing for US entry

# US allergy immunotherapy market represents a significant and attractive commercial opportunity

**\$2bn\*\***

estimated allergy immunotherapy market

**2-3m\*\*\***

Americans receive allergy immunotherapy

**>100 injections**

Current treatment: up to 100 injections over 3-5 years\*\*\*

**16%**

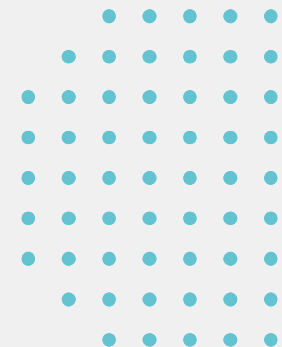
Some adherence levels as low as 16%\*

**None**

Currently no registered injected products

**\$300-400m\*\***

Estimated peak gross sales



\*Hankin CS, Cox L, Lang D, et al 2007 JACI

\*\*Internal estimate

\*\*\*Professor Lawrence DuBuske MD

# The changing US regulatory landscape offers potential for significant commercial growth

## Current US SCIT market



- **Home made, unlicensed** preparation
- **Non GMP** manufacturing
- **Non** registered
- **No** clinical evidence
- **Long** courses of treatment: **50 to 100** injections
- **Slow to act:** 6 to 12 months
- **Low** compliance

New USP and FDA regulations drive towards pharmaceutical grade, centrally manufactured, single allergen treatments

## Allergy Therapeutics' entry in the US



- **Standardised** dose vaccine
- **GMP** manufactured
- **FDA submission**
- **Multiple** clinical studies
- **Ultra- short course** treatment: **6** injections for optimal product profile
- **Efficacy** in 3 weeks
- **High** compliance



# Portfolio of products offer a strategic advantage to capture US opportunity

Grass



Ragweed



Trees



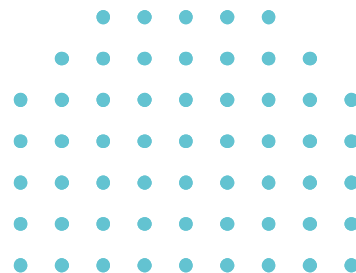
Mites



Peanut



- Proprietary, IP protected technology
- De-risked opportunity
  - Treated more than 250,000 patients and marketed in 7 countries (pollen)
- First mover advantage
  - First to market in the seasonal injected segment
  - High entry barriers: regulatory requirements for extensive trials on efficacy and safety
- Strategic fit for US market
- Building on progress to date in the US:
  - \$100m invested in clinical studies to date
  - 15 clinical trials completed to date, including Phase I, II & III successful studies
  - Investigated in over 3,000 patients worldwide, mainly in the US





# Financial Results

# P&L – year ended 30 June 2018

**+6.6%**

Solid sales performance  
in weak pollen season

**+£6.7m**

R&D  
expenditure up  
due to two key trials

**£9.3m**

Operating profit pre R&D

(2017: £7.4m) due to investment,  
leveraging solid sales

	2018 £'m	2017 £'m	Variance £'m	%
Revenue	68.3	64.1	4.2	7%
Gross profit	51.3	47.4	3.9	8%
Overheads	(42.6)	(40.7)	(1.9)	5%
R&D	(16.0)	(9.3)	(6.7)	
Other Income	0.6	0.7	(0.1)	
Operating loss	(6.7)	(1.9)	(4.8)	
Net Financing costs	(0.2)	(0.1)	(0.1)	
Tax	(0.6)	(0.5)	(0.1)	
Loss after tax	(7.5)	(2.5)	(5.0)	

# Sales – year ended 30 June 2018

		2018	2017	Variance	
		£'m	£'m	£'m	%
Stable sales growth					
Increases in Spain and Eastern Europe	Gross Revenue at Constant Exchange Rate	70.4	69.9	0.5	1%
Good growth in Venomil and Acarovac Plus	Rebate at Constant Exchange Rate	(4.0)	(5.8)	1.8	
	Net Revenue at Constant Exchange Rate	66.4	64.1	2.3	4%
Most markets performing robustly	Effect of Foreign Exchange	1.9		1.9	
	Net Revenue	68.3	64.1	4.2	7%
FX impact much lower in this period as smaller difference between rates	*Constant exchange rate Euro/£	1.16			
	Current exchange rate Euro/£	1.13	1.16		

\* Constant currency uses prior year weighted average exchange rates to translate current year foreign currency denominated revenue to give a year on year comparison excluding the effects of foreign exchange movements.

# Balance sheet at 30 June 2018

+17%

Inventory higher due to  
preparation for clinical trial  
material

£15.5m

Cash at year end 2018

£3.1m

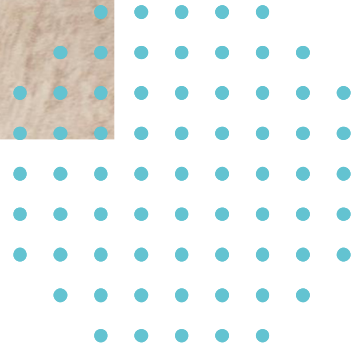
Debt. Seasonal overdraft  
in place (undrawn)

	2018 £'m	2017 £'m	Variance £'m
Non-current assets			
Property , plant and equipment	10.1	9.7	0.4
Intangible assets	4.9	5.5	(0.6)
Investments	5.1	4.5	0.6
	20.1	19.7	0.4
Current assets			
Inventories	8.8	7.5	1.3
Trade and other receivables	6.6	7.9	(1.3)
Cash	15.5	22.1	(6.6)
Liabilities			
Financial Liabilities	(3.1)	(3.3)	0.2
Other Liabilities	(24.9)	(23.9)	(1.0)
Net Assets	23.0	30.0	(7.0)
Equity			
Share capital and share premium	103.0	103.0	0.0
P&L account and other reserves	(80.0)	(73.0)	(7.0)
Total Equity	23.0	30.0	(7.0)



# Cashflow for the year ended 30 June 2018

	2018		2017	
	£'m	£'m	£'m	£'m
Positive net cash pre R&D generated by growth in business and foreign exchange benefit		22.1		23.4
	(6.9)		(2.0)	
	3.0		3.5	
		(3.9)		1.5
		0.4		(1.1)
		(0.3)		(0.2)
Significant tax received due to R&D tax credit from 2015 & 2016 financial year	0.1		0.0	
	(0.4)		(0.3)	
	(2.2)		(1.7)	
		(2.5)		(2.0)
	0.0		0.0	
	(0.3)		(0.2)	
		(0.3)		(0.2)
		0.0		0.7
Strong Cash position of £15.5m driven by solid performance and timing of R&D investment		15.5		22.1



# Summary and outlook



# Summary and outlook

## 2019 set to be a pivotal year

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Delivering against our strategy: three pillars to growth

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Robust financials set to continue

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Clinical trials progressing as planned – broad pipeline underpinned by innovative technologies

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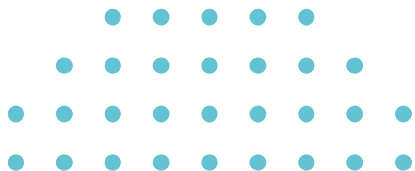
Focused strategy to be first to market in the US SCIT segment

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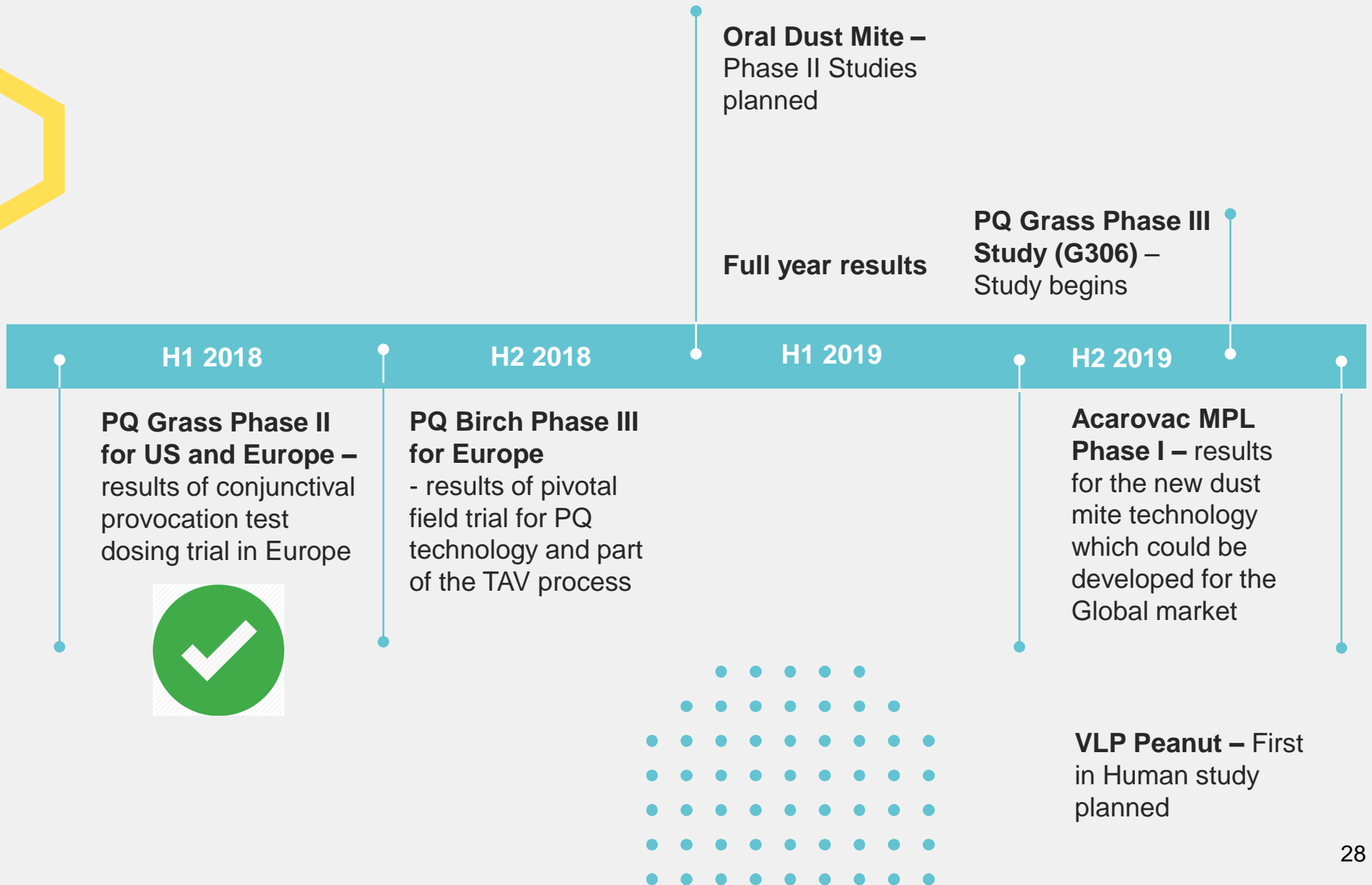
Board remains confident about Group's future prospects

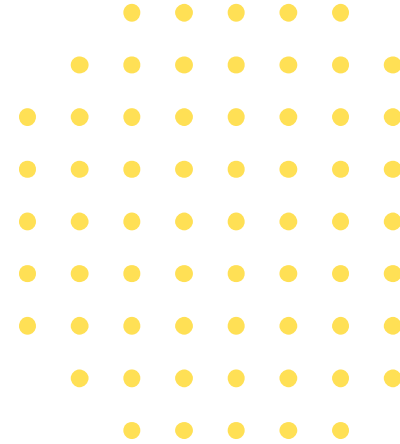
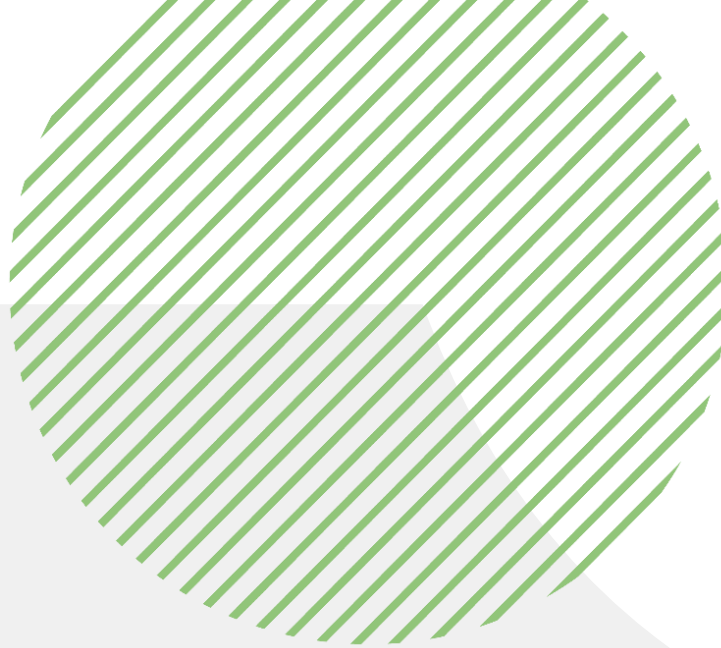
Continued gain in market share

Successful Phase II Grass Trial



# Key milestones





# Backup Slides

# Introduction

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Leading, fully integrated biopharmaceutical company based in the UK

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Provide treatments that have potential to cure disease, not just symptoms. Focus on moderate to severe patients

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PQ<sup>®</sup> Platform enabling ultra-short course treatment for grass, tree and ragweed allergies

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Headquartered in Worthing, Sussex with about 500 employees

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10% compound annual growth achieved over the last 19 years

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Leading provider of subcutaneous aluminium-free allergy vaccines

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Spun out of Smith Kline Beecham in 1999

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Market capitalisation of about £170m , AIM ticker LSE:AGY

R&D pipeline focussing on peanut allergy with VLP technology

# Cutting-edge Platform Technologies

	Modified Allergen (Allergoid)	Native Allergen	Recombinant Allergen	Microcrystalline Tyrosine (MCT)	Monophosphoryl Lipid A (MPL)	Virus-Like Particles (VLP)
<b>MATA</b>	✓			✓		
<b>MATA MPL (PQ)</b>	✓			✓	✓	
<b>Sublingual</b>		✓				
<b>Mite SCIT</b>	✓			✓		
<b>Mite SCIT + MPL</b>	✓			✓	✓	
<b>Venom SCIT</b>		✓				
<b>Peanut*</b>			✓	✓		✓

\* Product under pre-clinical investigation, full product profile yet to be determined

# Unique depot Microcrystalline tyrosine (MCT) provides aluminium alternative as well as adjuvant properties

## Patent protection for MCT

### Processing patent covers MCT

MCT particles are formulated as sterile in state of the art processes enabling defined particle morphology and size optimised for binding to wide variety of antigens.

MCT Process patent extended-UK (2032)/EU filing 2032

## R&D update Allergy / Non – Allergy indications

Within the last 12 months, studies have been completed supporting MCT use as a depot immunomodulator in each application:

Key publication in The Journal of Inorganic Biochemistry provides insight to the role of the (MCT) for use in existing and future therapeutic development incl. synergies with MCT and MPL in our Pollinex Quattro brand

Immunomodulation of MCT in allergy (publication pending 2016) – University of Zurich

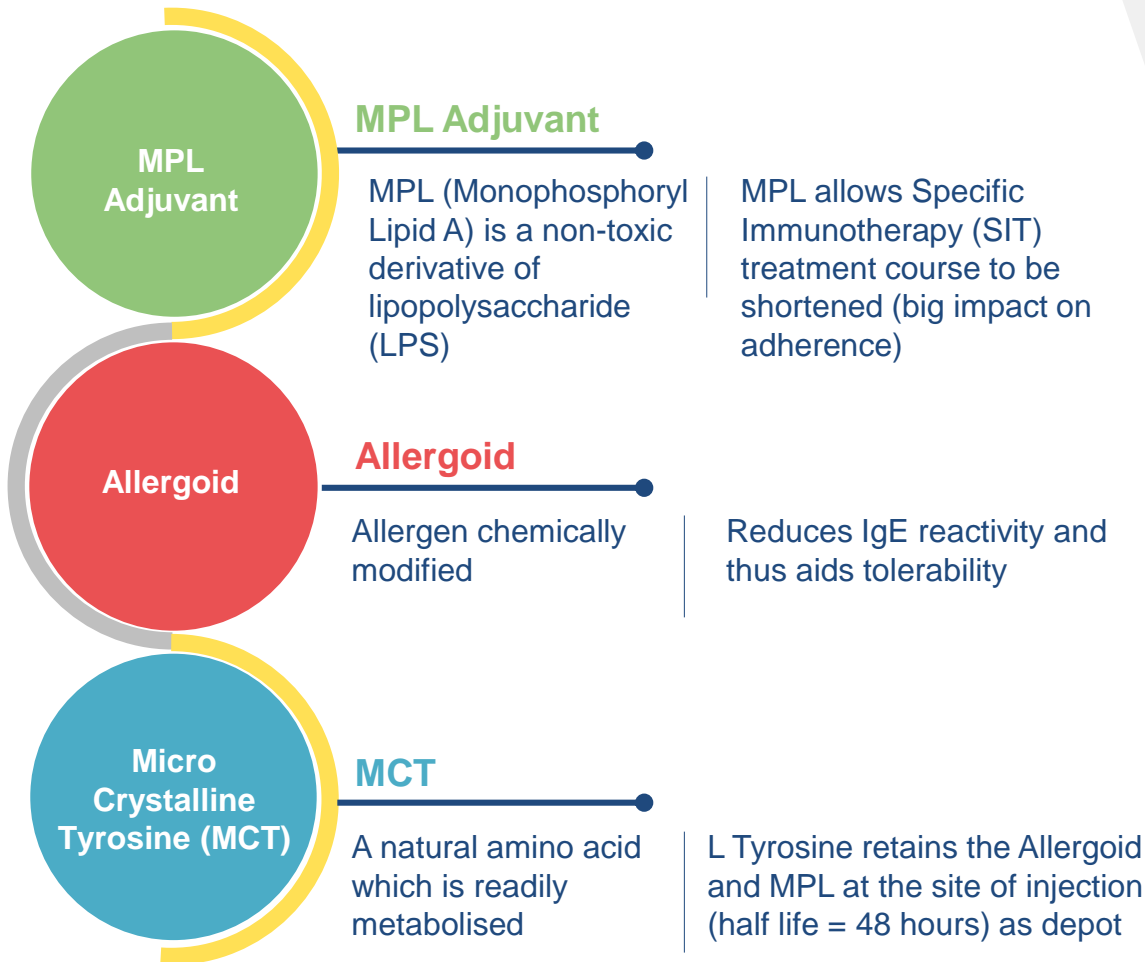
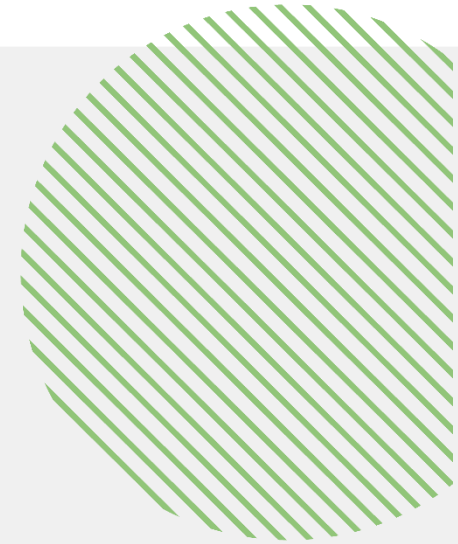
MCT improves efficacy in non-allergy models (Influenza, Malaria) – Public Health England, University of Oxford (Jenner Institute), respectively. (publication in preparation)

MCT to enhance immunogenicity of different vaccines – for malaria study





# PQ: Differentiated platform approach enhances compliance, leads to higher efficacy and successful outcomes



## Inclusion

- A history of moderate to severe symptoms of seasonal allergic rhinitis and/or conjunctivitis due to grass (*Pooideae*) pollen exposure that required repeated use of antihistamines, nasal steroids, and/or leukotriene modifiers for relief of symptoms during the last two consecutive seasons prior to the study, confirmed by patient records if available
- A positive skin prick test (SPT) for grass (wheals of  $\geq 5$  mm and histamine [wheal (longest diameter)  $\geq 3$  mm and a negative SPT to the negative control at screening
- Grass-specific IgE class  $\geq 2$  as documented by a immunoCAP or equivalent test at screening

## Exclusion

- A history of moderate to severe allergy symptoms occurring in the months of screening and treatment periods, and/or grass pollen season caused by perennial or seasonal allergens (other than grass) during the 3 years prior to Visit 1
- Exception: screening and/or treatment can be conducted outside of the pollen season(s) of concern or perennial allergies to cats and dogs are irrelevant due to avoidance measures

# Allergy Therapeutics: Company with Solid Sales and Global presence

Sales and marketing network comprising c.140 European sales force

