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# Delivering on our Strategy

Preliminary Results for the year

ended 30 June 2021

Allergy Therapeutics PLC



Manuel Llobet – Chief Executive Officer Nick Wykeman – Chief Financial Officer Alan Bullimore – Head of Business Innovation

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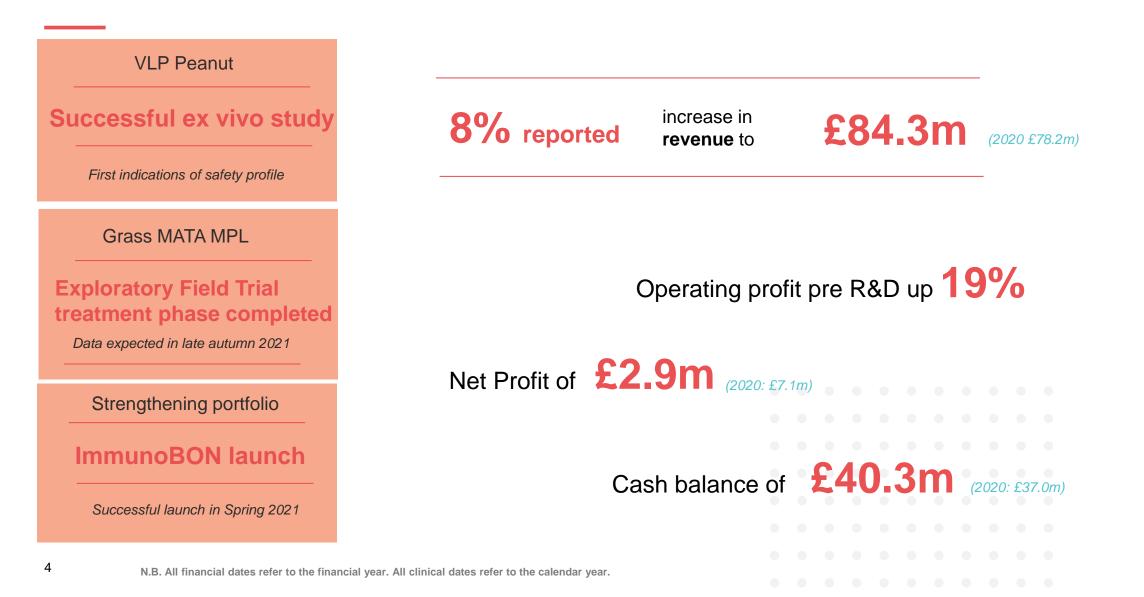
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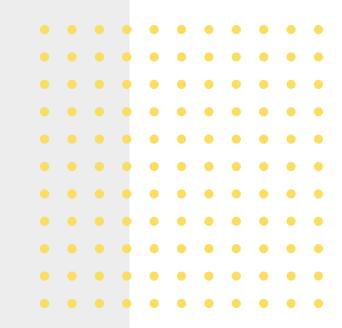
## **2021 Financial and Operational Highlights**





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# **Business and Strategy**



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

### J1

6

#### **Expanding in Europe**

Strongly performing profitable business

Growing market share and additional product registrations

Drive market position via world class supply chain and increased patient adherence



## 02

#### Strong pipeline

New technologies underpin pipeline breadth and depth

Investment strategy supported by growing revenue stream



#### **Preparing for US entry**

Allergy

Therapeutics PLC

Significant opportunity in largest allergy market

Develop market access approach and relationships

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



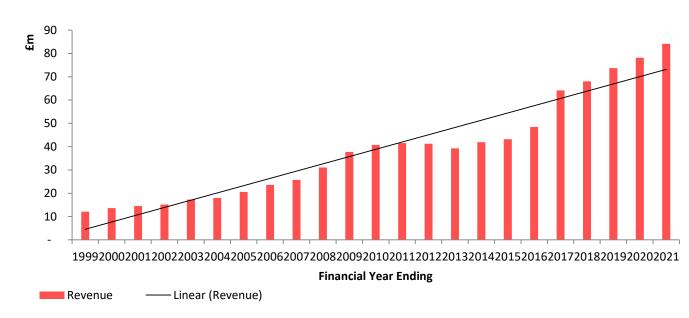


# Expanding in Europe

## **Robust European Business**

- Continued and strong growth in Germany and Austria while Southern Europe affected by COVID-19
- Successful ImmunoBON launches in Germany and Austria with potential to launch in other major European markets in the next year
- Business coped very well with challenges of COVID, Brexit and other regulatory changes
- Costs lower than expected in year due to COVID-19 restrictions
- 2022 sales growth likely to be low single digit due to streamlining of the product lines in the German market

9% CAGR growth over last 23 years since formation





# Pipeline progress

## Innovative, Broad Pipeline and Marketed Products



	Pre-clinical	Phase I	Phase II	Phase III	Market	/Regist	ered	Also available as a Named Patient Product
Grass MATA	Short	-course SCIT						
Tree MATA	Short	-course SCIT			1			
Ragweed MATA	Short Short	-course SCIT						
Bee Venom SCIT	Short	-course SCIT						
Wasp Venom SCIT	Short	-course SCIT						
Grass MATA MPL	Short	course Grass SCIT with	n 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					
Peanut SCIT	Short-course Peanut SCIT			• •	•			•
Melanoma SCIT				• •	• •			•
Asthma SCIT				• •	• •			•
Psoriasis SCIT				• •	•			
Atopic dermatitis SCIT				• •				
SCIT: Subcutaneous Ir MATA: Modified Allerge								

# VLP Peanut: a potential next generation peanut allergy immunotherapy

Successful primary outcome in Imperial biomarker study

Study demonstrates VLP Peanut's hypoallergenic potential with 24-fold reduction in basophil activation and histamine release

Results add to positive preclinical data package which demonstrated strong immunologic protection after just one dose IND submission to US FDA expected late 2021

Manufacturing batch scale up successfully achieved

First in-human study on track for Q1 2022 (PROTECT)

> VLP Peanut - a new opportunity in a \$8bn\* global food allergy market

# Peanut Study Results: evaluating biomarkers from peanut allergic patients

- Ex-vivo study using blood samples from peanut allergic patients
- 24-fold reduction in basophil activation and histamine release after VLP Peanut compared to Ara h 2 (the major peanut allergen)
- Target was a 10-fold reduction
- Provides strong support for the hypo-allergic mode of action
- Ex-vivo data for VLP Peanut demonstrates a potent immune stimulating mode of action indicative of a beneficial efficacy profile
  Demonstrates reduced ability to trigger immune cells associated with the allergic condition compared to whole peanut extract
  Allergy Therapeutics

### **Grass MATA MPL**

Completion of treatment phase in exploratory field study (G309) with results expected autumn of 2021

Efficacy field study (G306) to start H2 2022 incorporating learnings from G309

Both Grass G309 and G306 fully funded

Product is one Phase III efficacy trial and completion of safety database away from filing in US

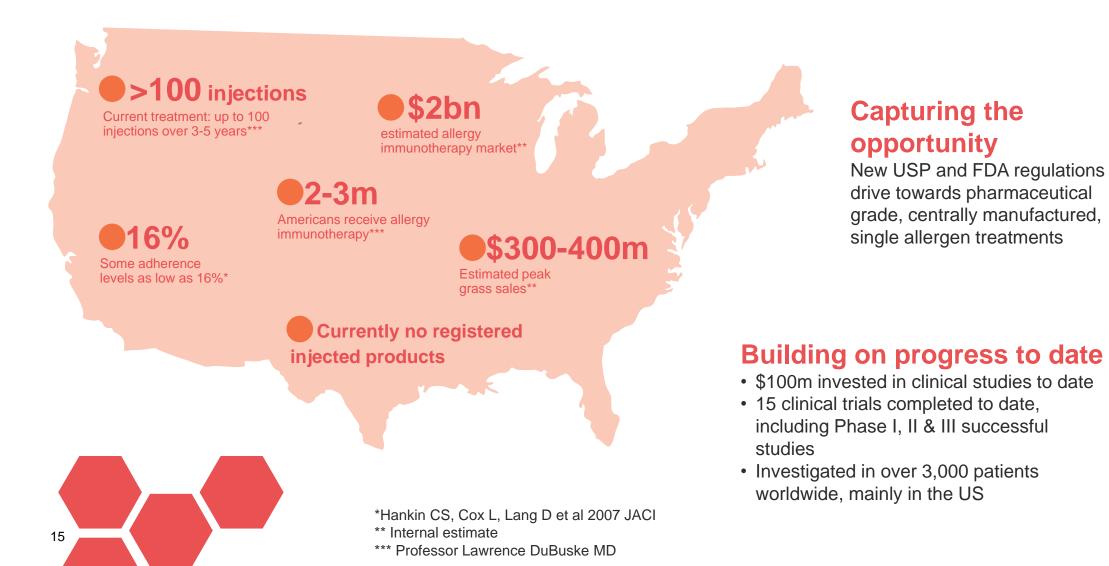
**Key product for US introduction –** Ragweed and Birch would be products to follow with INDs already open and Phase II data available Allergy Therapeutics

Ultra short-course product with huge potential in US market



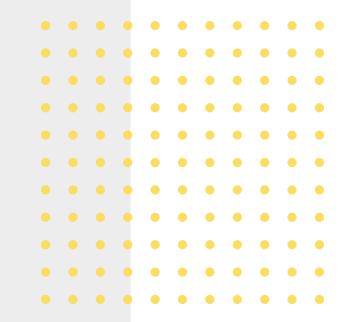
# Preparing for United States

### **Preparing for US entry**



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# Ensuring Sustainable Long-Term Value



## Adopting an ESG Framework

#### Environmental

- Become a Net Zero Carbon emission Company by 2030
- Manufacturing sites have reduced all single use plastic and are reusing water
- Planning permission granted to build energy centre in Worthing
- Working towards paperless offices across all sites (fully paperless in Spain and Italy)
- Using biodegradable adjuvants (MCT)

#### Social

- Set gender diversity targets for our Board and Executive Team - 30% Board and 50% Exec Team by 2025
- Work closely with local schools in Worthing area to raise awareness of careers in STEM
- Introduced mental health first aiders across group
- Focussed on better employee engagement and wellbeing introducing a 'wellness day off' and fitness challenges

#### Governance

- Created a more robust compliance framework with additional controls relating to ethical decision-making and anti-bribery
- Annual review of effectiveness and twice a year assessment of Board composition to ensure that it is right to achieve our future goals
- Improve risk management processes for consistency across the Group and more robust systems of internal controls

#### Focus areas and expected actions in 2021-2022

- Introduce ESG framework which will include an Executive ESG Steering Committee
- ESG materiality assessment finalised
- UN Sustainable Development Goals adopted to align with AGY strategy and help guide policy and decision making
- Sustainability strategy approved by Board and communicated to stakeholders
- Net Zero Carbon emission pathway fully costed and timelines defined to 2030
- Measurable targets and actions for Diversity, Equity & Inclusion agreed

Measurable targets and actions for Diversity, Equity & Inclusion agreed

**Financial Results** 

## P&L – year ended 30 June 2021



		2021 £'m	2020 £'m	Variance % £'m	
+8%	Revenue	84.3	78.2	6.1	8%
Solid reported sales performance	Gross profit	62.2	58.0	4.2	7%
	Overheads	(45.9)	(44.5)	(1.4)	3%
+3%	R&D - Expenditure	(12.9)	(9.0)	(3.9)	
costs due	- Settlement		3.2	(3.2)	
restrictions	Other Income	0.6	0.6	0.0	
£16.9m	Operating profit	4.0	8.3	(4.3)	
Operating profit pre R&D	Net Financing costs	(0.3)	(0.2)	(0.1)	
£'m    £'m    £'m      +8%    Revenue    84.3    78.2    6.1      Solid reported sales performance    Gross profit    62.2    58.0    4.2	0.2				
19	Profit after tax	2.9	7.1	(4.2)	

# Balance sheet at 30 June 2021

£0.7m Increase in inventory due to

extended Brexit supply chain

# £40.3m

Cash at year end 2021 (2020 : £37.0m)

£3.4m

Debt. Seasonal overdraft in place (undrawn)

		Ther	apeutics PLC
	2021	2020	Variance
	£'m	£'m	£'m
Non-current assets			
Property , plant and equipment	19.7	20.4	(0.7)
Intangible assets	4.7	4.7	0.0
Investments	5.8	5.9	(0.1)
Current assets	30.2	31.0	(0.8)
Inventories	10.8	10.1	0.7
Trade and other receivables	6.2	8.1	(1.9)
Cash	40.3	37.0	3.3
Derivative instruments	0.5		0.5
Liabilities			
Financial Liabilities	(11.2)	(12.2)	1.0
Other Liabilities	(28.3)	(30.2)	1.9
Net Assets	48.5	43.8	4.7
Equity			
Share capital and share premium	113.2	113.2	0.0
P&L account and other reserves	• (64.7) • • •	(69.4)	4.7
Total Equity	48.5	43.8	4.7

Allergy

# Cashflow for the year ended 30 June 2021

Positive net cash pre R&D generated by growth in business and low costs due to COVID

Capital expenditure in line with last year

Strong Cash position of £40.3m driven by solid performance and low costs

		2021	2020	)	
	£'m	£'m	£'m	£'m	
Opening cash balance 1 <sup>st</sup> July		37.0		27.4	
Profit before tax	3.7		8.1		
Adjustments re operations	4.7		5.3		
Net cash generated by operations		8.4		13.4	
Tax received/paid		0.1		(0.9)	
Interest paid		(0.2)		(0.2)	
Interest received	0.1		0.3		
Investments and acquisitions	(0.2)		(0.5)		
Capital expenditure	(2.5)		(2.3)		
Net cash used in investing activities		(2.6)		(2.5)	
Interest on leases	(0.3)		(0.3)		
Net movement in borrowings	(1.7)		(0.1)		
Net cash generated/(used) in financing activities		(2.0)		(0.4)	
Effects of exchange rates on cash		(0.4)		0.2	
Closing Cash Balance 30 June		40.3	 	37.0	



## Conclusion

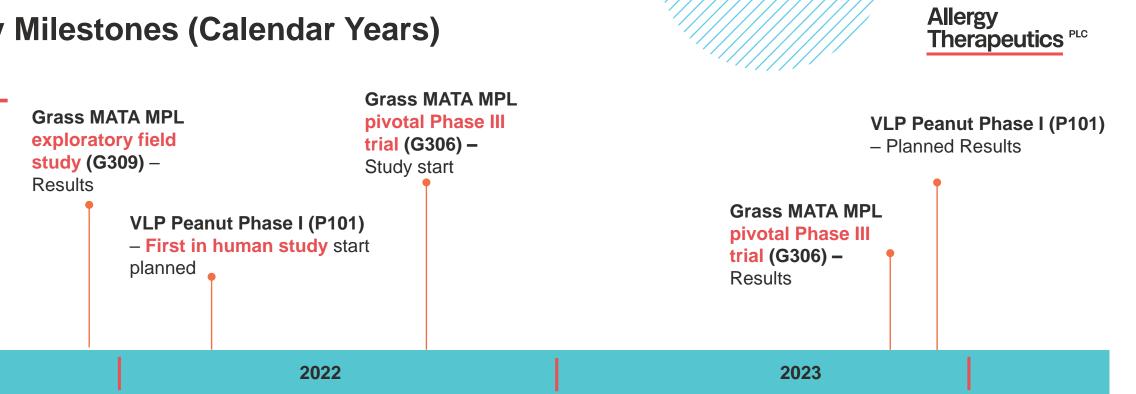
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## 2022 Year

- Upcoming IND Meeting with FDA for VLP
  Peanut
- Initiation of Peanut Phase I trial (PROTECT)
- Read out of Grass MATA MPL G309 trial and start of pivotal G306 trial
- ImmunoBON additional EU launches and further data generation/indication expansion
- Maintaining focus on SCIT and innovative approaches to allergy treatment



### **Key Milestones (Calendar Years)**



Interim reports on progress of VLP Peanut Phase I (PROTECT) expected across trial



Allergy Therapeutics

<u>Q&A</u>



# Appendix

## **Allergy Therapeutics**

Leading, fully integrated biopharmaceutical company based in the UK

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

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

Headquartered in Worthing, Sussex with about 600 employees 9% compound annual revenue growth achieved over the last 23 years

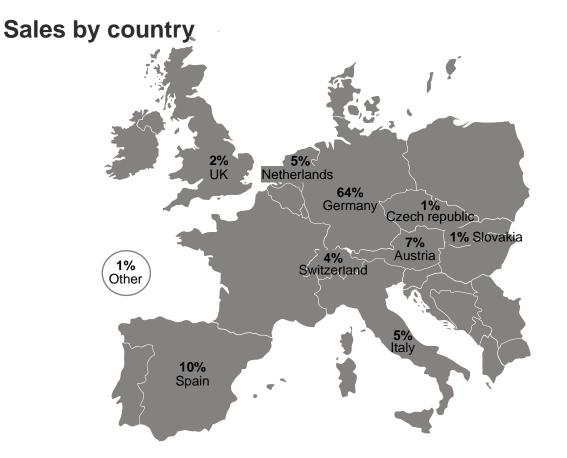
Leading provider of subcutaneous aluminiumfree allergy vaccines

Spun out of Smith Kline Beecham in 1999

Market capitalisation of about £220m, AIM ticker LSE:AGY R&D pipeline focussing on peanut allergy with VLP technology

### Sales breakdown for FY 2021



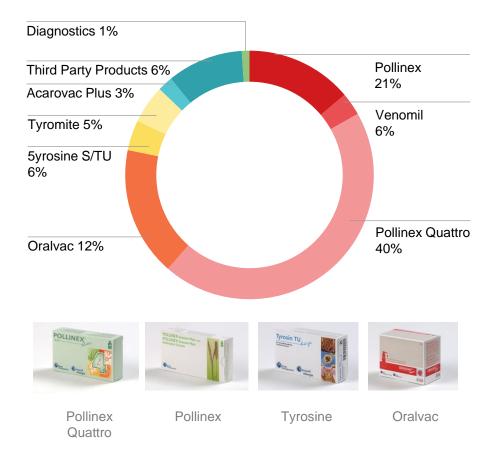


 $^1$  Sales breakdown based on gross sales at budget exchange rates (before freight, rebates and exchange) : £84.0 million.

After deducting rebates, freight charges and foreign exchange adjustments, total sales for FY2021 is £84.3million

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

#### Sales of £84.3m by product<sup>1\*</sup>



### **Cutting-edge Platform Technologies**

Modified Allergen (Allergoid)	Native Allergen	Recombinant Allergen	Microcrystalli ne Tyrosine (MCT)	Monophospho ryl Lipid A (MPL)	Virus-Like Particles (VLP)	Lipocalin Technolog
			<b>~</b>			
			<b></b>			
						•••
			1			
	Allergen (Allergoid)	Allergen (Allergoid)  Native Allergen    Image: Constraint of the second s	Allergen (Allergoid)  Native Allergen  Recombinant Allergen    Image: Combinant Allergen  Image: Combinant Allergen    Image: Combinant Allergen  Image: Combinant A	Allergen (Allergoid)Native AllergenRecombinant Allergenne Tyrosine (MCT)Image: Straight of the st	Allergen (Allergoid)Native AllergenRecombinant Allergenne Tyrosine (MCT)ryl Lipid A (MPL)Image: Straight of the stra	Allergen (Allergoid)Native AllergenRecombinant Allergenne Tyrosine (MCT)ryl Lipid A (MPL)Particles (VLP)Image: Combinant AllergenImage: Combinant AllergenImage: Combinant AllergenImage: Combinant (MCT)Image: Combinant (MPL)Particles (VLP)Image: Combinant AllergenImage: Combinant AllergenImage: Combinant AllergenImage: Combinant (MCT)Image: Combinant (MPL)Particles (VLP)Image: Combinant AllergenImage: Combinant AllergenImage: Combinant AllergenImage: Combinant (MCT)Image: Combinant (MCT)Image: Combinant AllergenImage: Combinant AllergenImage: Combinant AllergenImage: Combinant (MCT)Image: Combinant (MCT)Image: Combinant AllergenImage: Combinant AllergenImage: Combinant AllergenImage: Combinant (MCT)Image: Combinant (MCT)Image: Combinant AllergenImage: Combinant AllergenImage: Combinant AllergenImage: Combinant (MCT)Image: Combinant (MCT)Image: Combinant AllergenImage: Combinant AllergenImage: Combinant (MCT)Image: Combinant (MCT)Image: Combinant (MCT)Image: Combinant AllergenImage: Combinant (MCT)Image: Combinant (MCT)Image: Combinant (MCT)Image: Combinant (MCT)Image: Combinant AllergenImage: Combinant (MCT)Image: Combinant (MCT)Image: Combinant (MCT)Image: Combinant (MCT)Image: Combinant AllergenImage: Combinant (MCT)Image: Combinant (MCT)Image: Combinant (MCT)Image: Combinant (MCT)Image: Combinant AllergenImage: Combinant (MCT)Image: Co

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

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#### 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

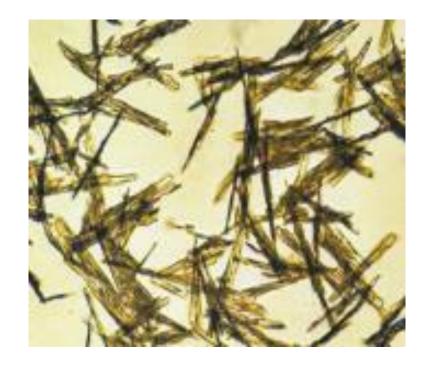
#### **R&D** update Allergy / Non – Allergy indications

Studies have been completed supporting MCT use as a depot immunomodulator in each application:

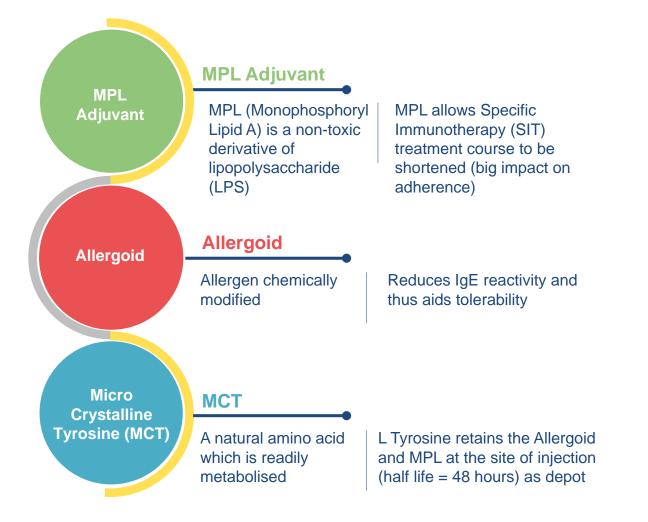
> Key publication in The Journal of Inorganic Biochemistry provides insight to the role of the (MCT) for use in existing and future therapeutic development incl. synergies with MCT and MPL in our Pollinex Quattro brand

MCT improves efficacy in non-allergy models (Influenza, Malaria) – Public Health England, University of Oxford (Jenner Institute), respectively. (publication in preparation) Immunomodulation of MCT in allergy (publication pending 2016) – University of Zurich

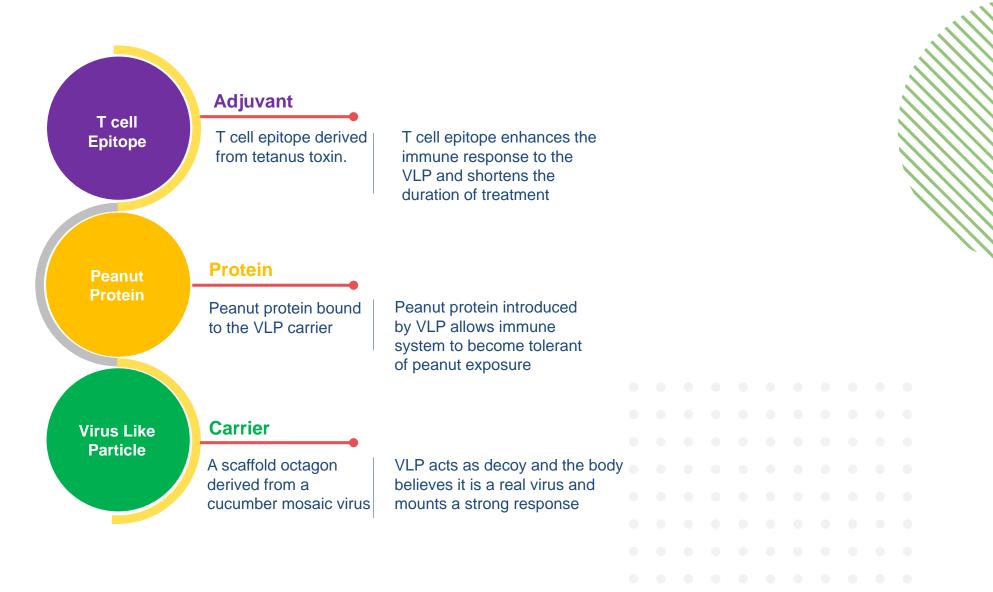
MCT to enhance immunogenicity of different vaccines – for malaria study



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



### **Peanut VLP**





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

#### Allergy Therapeutics PLC



- 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



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

## Virus like particle (VLP) platform

# Sophisticated technology with potential to treat severe and extreme allergies

- Engineered with a T-cell epitope derived from the tetanus toxin
- Leads to activation of memory cells
- Increased antibody response

When bound with an allergen, the immune system reacts to the virus not the allergen.

Therefore protective immunity is induced, enabling shorter therapy duration with an enhanced tolerability profile.

**Potential allergy areas** include peanut, mixed nuts, cat, mould, mite and venoms

Initial peanut results show potential of technology

# Allergy Therapeutics: Company with Solid Sales and Global presence

Allergy Therapeutics PLC

Sales and marketing network comprising c.140 European sales force

