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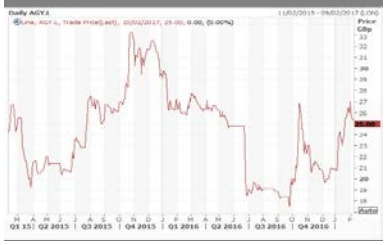
Pharmaceuticals & Biotechnology



Source: Eikon Thomson Reuters

Market data	
EPIC/TKR	AGY
Price (p)	25.0
12m High (p)	28.5
12m Low (p)	17.3
Shares (m)	593.4
Mkt Cap (£m)	148.4
EV (£m)	129.5
Free Float*	38%
Market	AIM

**As defined by AIM Rule 26*

Description

AGY provides information to professionals related to prevention, diagnosis and treatment of allergic conditions with special focus on allergy vaccination and a successful treatment dealing with the underlying cause and not just the symptoms.

Company information

CEO	Manuel Llobet
CFO	Nick Wykeman
Chairman	Peter Jensen
	+44 1903 845 820
	www.allergytherapeutics.com

Key shareholders

Directors	0.7%
Abbott Labs	40.5%
Southern Fox	21.1%
Odey	7.4%
Invesco	5.7%
Blackrock	3.2%

Diary

20 Jan	Hardman report
29 March	Interims
Sept-17	Finals

Analysts

Martin Hall	020 7148 1433
	mh@hardmanandco.com
Dorothea Hill	020 7148 1433
	dmh@hardmanandco.com
Gregoire Pave	020 7148 1434
	gp@hardmanandco.com

Allergy Therapeutics

Disruptive peanut allergy vaccine

AGY is a long-established specialist in the prevention, diagnosis and treatment of allergies. Trials to obtain full regulatory approval as a biological for its ultra short-course immunotherapy, Pollinex Quattro, have progressed well in the EU, and are back on-track in the US with a planned new safety trial. Meanwhile, AGY acquired novel virus-like particle (VLP) technology with the goal to develop a short-course therapeutic vaccine for peanut allergy. Positive safety and efficacy results from proof-of-concept pre-clinical tests with Polyvac Peanut are very encouraging. A small safety study in humans is required before Phase I trials can commence.

- **Peanut allergy:** Peanut allergy has emerged over the last 40 years and it is thought that there are an estimated 4 million sufferers in the US alone, of which 2-3 million are children. Peanut allergy is the number one cause of death from food reactions.

- **VLP technology:** Although AGY is one of the leading global authorities in immunotherapies against a number of allergens, it did not have anything in its armoury for peanut allergy. Therefore, in November 2015, it acquired a licence to develop novel VLP technology for use as an adjuvant for a peanut vaccine.

- **Proof-of-concept:** AGY has made rapid progress over the last 15 months, identifying a lead VLP adjuvant and combining it with recombinant peanut allergen to create a single dose, subcutaneously administered, therapeutic vaccine which has given positive safety and efficacy results in pre-clinical tests.

- **Next steps:** AGY will enter discussions with the regulator about recruitment of patients into a required small safety study with Polyvac Peanut. This preludes commencement of Phase I development, in-line with the strategic development plan provided at the time of the last funding round.

- **Investment summary:** AGY is well positioned to benefit from the change in regulatory attitude towards therapeutic allergy vaccines, particularly in the US where the market is largely unregulated. Meanwhile it is expanding its expertise in short-course immunotherapy into areas of unmet medical need and Polyvac Peanut has the potential to disrupt the current $8bn peanut allergy market.

Financial summary and valuation

Year end June (£m)	2014	2015	2016	2017E	2018E	2019E
Sales	41.96	43.23	48.51	62.5	69.1	77.8
R&D spend	-2.96	-3.12	-16.22	-10.5	-15.0	-16.0
Underlying EBIT	1.39	2.91	-12.06	-4.2	-7.3	-8.1
Reported EBIT	1.21	1.41	-12.38	-4.2	-7.3	-8.1
Underlying PTP	1.27	2.84	-12.17	-4.3	-7.5	-8.3
Statutory PTP	1.08	0.65	-12.06	-4.3	-7.5	-8.3
Underlying EPS (p)	0.20	0.48	-2.31	-0.9	-1.5	-1.6
Statutory EPS (p)	0.16	0.02	-2.29	-0.9	-1.5	-1.6
Net (debt)/cash	2.25	20.14	18.86	10.9	0.7	-12.4
Shares issued	0.00	20.08	10.97	0.3	0.3	0.3
P/E (x)	122.0	51.8	-10.8	-27.5	-17.0	-15.4
EV/sales (x)	3.1	3.0	2.7	2.1	1.9	1.7

Source: Hardman & Co Life Sciences Research

Polyvac Peanut allergy vaccine

Peanut allergy: 0.5-1% prevalence

Source: Allergy Therapeutics

In November 2015, Allergy Therapeutics acquired the licence to virus-like particle (VLP) technology with a view to using it to develop a vaccine immunotherapy for peanut allergy. At that point in time, although AGY was a leading authority in short-course subcutaneous immunotherapy (SCIT) against a number of allergens, it did not have anything in its armoury to tackle one of the commonest causes of allergies worldwide, peanuts. The company has made considerable progress since acquiring this licence and has announced that its therapeutic peanut allergy vaccine, Polyvac Peanut, has passed pre-clinical proof-of-concept testing.

Background

Peanut allergy is a major problem resulting in a number of fatalities each year

Peanut allergy affects more than four million people in the US alone, with over 50% being children. It is particularly prevalent in western cultures. Anaphylaxis from peanut allergy is the number one cause of death from food reactions[1]. Barely recognised 50 years ago, there is a train of thought that the rise of peanut allergy in children may be directly related to the use peanut oil as an adjuvant in childhood vaccines, which was added to promote the immune response. Indeed, historically, it became a preferred excipient in pharmaceutical vaccines from the 1980s, which coincided with a dramatic increase in the schedule of vaccinations in children[2]: its rapid speed of onset means that prophylactic immunisation is the most effective intervention strategy. At present, there are no approved peanut allergy vaccines, thus the unmet need is large on a global scale.

VLPs are safe and effective adjuvants

Multiple vaccines incorporating VLPs, a safe and effective adjuvant technology that induces strong T- and B-cell immune responses, are FDA approved e.g. Cervarix (GSK) for human papillomavirus. As part of the overall R&D programme, AGY has been developing its peanut allergy vaccine, Polyvac Peanut, beginning proof-of-concept studies in 2016 with the view to entering clinical trials as soon as possible.

Pre-clinical update

Polyvac Peanut…only product to be administered subcutaneously

Polyvac Peanut is innovative as an allergy vaccine as it is delivered subcutaneously and aims to induce protective immunity. This means that fewer immunizations should be needed – a 'short course SCIT' – reducing the duration of the therapy while simultaneously enhancing its safety profile. If successful, this approach could redefine the market for food allergy products. Competitor approaches to peanut vaccines involve repeated or prolonged exposure via oral or intra-dermal administration. The short-course approach with Polyvac Peanut is considered to have a number of advantages, positioning it well to take a large share of the estimated $8bn annual peanut allergy market.

VLP adjuvant

The candidate vaccine uses VLP as a carrier to present recombinant peanut allergen to the immune system. In this case, the VLP is derived from a bacteriophage (viruses that infect bacteria only) that does not include any viral genetic material. They are therefore unable to replicate within people. They consist of a capsid that displays high density viral surface proteins, that are recognised by the immune system, combined with peanut allergens, introduced using recombinant genetic technology. VLPs are easily produced via multiple cell culture systems.

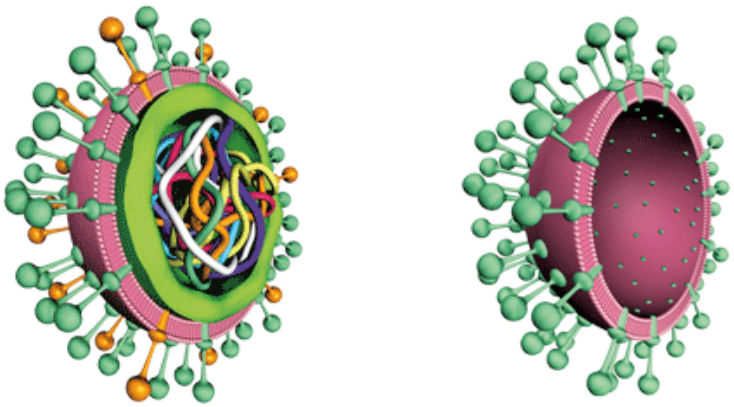
[1] The Peanut allergy epidemic. Fraser, H. Skyhorse 2011.
[2] www.thedoctorwithin.com

To quote the business development manager of Medicago, a Canadian biotechnology firm specialising in VLP-based vaccines:

"….VLP represents one of the most exciting emerging vaccine technologies for generating effective and long-lasting protection…."

Source: www.medicago.com

VLP technology



Virus containing nucleic acid | **Virus-like particle (VLP)**

Source: Medicago

Pre-clinical proof-of-concept

Polyvac Peanut reinforces AGY's specialisation in sub-cutaneous immunotherapy

AGY specialises in subcutaneous immunotherapy (SCIT) in which patients receive a course of injections over a prolonged period to desensitize them from their allergy. Results from pre-clinical proof-of-concept studies with its novel therapeutic peanut allergy vaccine, Polyvac Peanut, have been released to the market. A single dose of AGY's VLP adjuvant combined with recombinant peanut allergen was used in the tests and challenged with peanut.

- Polyvac Peanut was found to be safe and effective
- Those vaccinated with candidate vaccine had significantly better symptom scores than placebo
- The vaccine was shown to be hypoallergenic – it did not induce anaphylaxis in peanut-sensitised subjects in intravenous challenge

Looking to move into man

These are encouraging results using the company's state-of-the-art VLP technology and augur well for the human studies. AGY is discussing patient recruitment for a first-in-man safety trial with the regulator - the primary outcome will be measurement of patient safety, after which it will proceed to Phase I development.

Conclusion

AGY has made considerable progress since acquisition of the novel VLP technology specifically to pave the way to a peanut allergy vaccine. Polyvac Peanut is focused on the subcutaneous application of recombinant peanut allergen combined with the VLP adjuvant with the goal of developing a short-course peanut allergy immunotherapy. The aim of this approach is to induce protective immunity, enabling shorter duration of therapy which would be disruptive for the current peanut allergy market. Although these data represent the first step in a long process, they reaffirm AGY's position as a global leader in novel adjuvants for use in therapeutic vaccines.

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Hardman & Co Research Limited (trading as Hardman & Co)
11/12 Tokenhouse Yard
London
EC2R 7AS
T +44 (0) 207 929 3399

Follow us on Twitter @HardmanandCo

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Hardman & Co

11/12 Tokenhouse Yard
London
EC2R 7AS
United Kingdom

Tel: +44(0)20 7929 3399
Fax: +44(0)20 7929 3377

www.hardmanandco.com