

# O ImmuPharma \*\*

# Developing Innovative Peptides March 2017

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### Company summary

- Pharma development company listed on AIM since 2006 (LSE:IMM)
- Lead drug candidate, Lupuzor<sup>™</sup>, for the treatment of Lupus, a life threatening autoimmune disease **100% owned** 
  - Phase III pivotal study ongoing
  - Substantial 'blockbuster' market potential
- P140 platform with potential to target further auto immune diseases e.g. Crohn's disease
- Nucants platform with two Phase I trials completed for potential use in combination cancer treatments and in age related macular degeneration (AMD) and diabetic retinopathy
- Peptide technology platform
- Longstanding collaboration with Centre Nationnal de la Recherche Scientifique (CNRS)
  - Europe's largest research institution = ImmuPharma's 'Research Engine'
- Experienced management and research team
- Low-cost business model based on outsourcing (c. 20 people)

Continued value creation

March '17

£4.1m Equity Placing

Oct '16:

£3.5m Vendor Placing & Equity Issue

Feb '16: £8.4 million Placing & Subscription



52p

### Pipeline overview



#### Forigerimod/P140

- Lupuzor<sup>™</sup>
- Treatment of Lupus
- Unmet opportunity
- Phase III trial started



Potential for other autoimmune diseases

#### **Nucants**

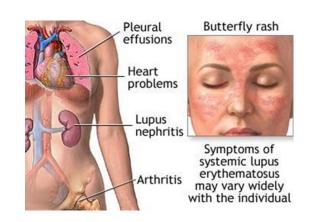
- IPP-204106
- Family of peptides for cancer and ophthalmology
- Phase IIa completed
- Potential for Phase II studies in cancer and AMD and/or diabetic retinopathy
- Potential for other indications

#### **Peptide Platform**

- R&D peptide platform developing foldamers
- Discovery
- Diabetes
- New patents filed

### What is Lupus?

- Lupus is an autoimmune chronic inflammatory disease, sometimes fatal, associated with disorders of the immune system
- Unmet market need, due to the lack of safe and effective treatments
- Multi-billion sales potential
- Varying patient estimates\*:
  - an estimated 5 million people globally suffer from lupus
  - 1.5 million lupus sufferers in Europe/US/Japan
- Current drugs have serious side-effects and limited effectiveness
- GSK's approval of Benlysta paves the path to market

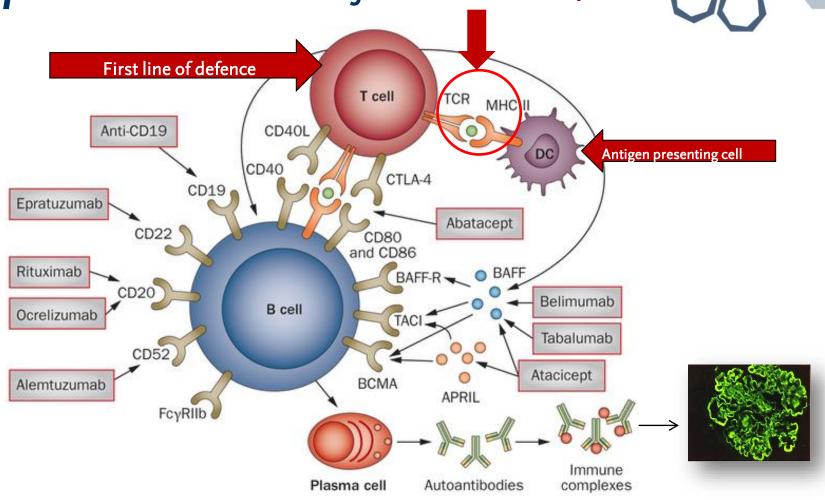


<sup>\*</sup> source: Lupus Foundation of America 'www.lupus.org' (2017)

### Lupuzor<sup>™</sup>

- Lupuzor™ or 'Forigerimod' is a 21 aa peptide (chemically synthesized)
- Novel mechanism that modulates the immune system by avoiding the activation of auto-reactive T-cells
- Phase IIb demonstrated a significant efficacy in the treatment of Lupus together with outstanding safety
- Lupuzor<sup>™</sup> granted Fast Track status by the US FDA and approval for pivotal phase III trial under Special Protocol Assessment
- Strong patent protection
- Final step prior to filing for marketing approval

Lupuzor™ - mechanism of action P140 / Lupuzor™ (



(New) therapeutics: most if not all target B cells

### Competitive landscape

#### **Current Standard of Care:**

- Low-dose steroids, immunosuppressants (e.g. methotrexate) and anti-malarials
- Limited efficacy: 60% of patients are not adequately treated

#### Other choices:

- Benlysta GSK's approved drug
  - Monoclonal antibody intravenous infusion
- High-dose steroids

Urgent need for new and better treatments



# O<sub>lmmuPharma</sub> Oob Lupuzor™ phase IIb final data

|                                  | Lupuzor™         | Benlysta*          |
|----------------------------------|------------------|--------------------|
| Duration of treatment            | 3 months<br>N=86 | 12 months<br>N=548 |
| Drop-out rate % (active/placebo) | 8% / 16%         | 23% / 25%          |
| % Responder active               | <b>62</b> %      | 43%                |
| % Responder placebo              | 38%<br>p < 0.025 | 33%<br>p < 0.025   |
| Clinical impact                  | + 25%            | + 10%              |

Based on published data: Lupuzor (Zimmer et al. 2012); Benlysta (Furie et al. 2011) \* Phase III study

#### Attractive economics

- Lupus patients are treated by specialists, not GPs = low marketing costs
- Long term treatment creates high costs to the community
- Benlysta priced at approx. US\$30,000 / per patient / per year
- Lupuzor<sup>™</sup> anticipated to have lower pricing
- High margin
- Using the Rheumatoid Arthritis (RA) Market as a case study:
  - Lupus, RA as well as Sjögren patients (no treatment available) have interconnected diseases and share the same physiopathology mechanism corrected by Lupuzor
  - RA drugs have achieved multi-billion annual sales\* (Humira US\$14bn, Remicade US\$6.6bn, Enbrel US\$5.4bn) \*2015 (Source: Labiotech.EU)

#### Route to market

Lupuzor™ can be marketed by:

- A global licensee, offering ImmuPharma royalties on sales (similar to US \$500m + Cephalon deal in 2009)
- ImmuPharma controlling manufacture using local distributors, retaining a higher margin
- Being acquired by Big Pharma

### Lupuzor™ phase III trial

- Phase III ongoing 28 investigator sites
  - 11 centres in the US
  - 16 centres in Europe
  - 1 centre in Mauritius
  - Simbec-Orion (CRO) experts in Lupus trials
- Protocol agreed with the FDA
  - One year dosing
  - Protocol similar to that of Phase IIb
  - n = 200 patients/study
  - Double-blind, Randomised, Placebo controlled; once a month (dose 0.2mg)
- Top line data expected during Q1 2018







### Lupuzor™ phase III trial - study highlights

- 200 patients successfully recruited and randomised (dosed)
  - 293 patients initially screened illustrating the demand from physicians for a new safe and effective treatment for Lupus
- 7 Countries and 28 sites are participating in the study
  - US: 11 sites with 70 patients randomised
  - Europe: 5 Countries and 16 sites with 81 patients randomised
  - Mauritius: 1 site with 49 patients randomised
- Study status as at the end of January 2017
  - over 80% of patients will have been treated for at least 3 months
  - 2 patients have completed the study
  - 24 patients will have been treated for 9 months
  - 50 patients will have been treated for 6 months
  - 90 patients will have been treated for 3 months
- To date no drug (active or placebo) related 'Serious Adverse Events' have been reported. This is
  consistent with the strong safety profile of Lupuzor™ shown in its earlier Phase IIb study



### Lupuzor™ key milestones



- US sites open and recruitment commences
- Investigator Meeting



- First dosing of US patients
- European sites open and recruitment commences
- First European patients dosed
- Additional site in Mauritius
- Completion of recruitment of 200 patients

2017

• Further progress updates on trial



- Last patient completes treatment
- Top-line Phase III results



#### Investment rationale

- Lupuzor™ is a potential blockbuster asset 100% owned by ImmuPharma
- Pivotal phase III trial on track
- Awarded 'Gold Standard' Special Protocol Assessment and Fast Track designation by FDA
- Competitive, efficacy & safety profile
- Collaboration partnership with CNRS
- P140 platform provides potential to expand into other autoimmune diseases
- · Earlier stage development pipeline from pre-clinical through to Phase II
- Value enhancing news-flow anticipated over medium term
- Intensive IR strategy ongoing





### **Appendix**

### Management team



Tim McCarthy
Non-Executive Chairman

35 year international business career in high growth biotech, healthcare and technology companies. Former Chief Executive Officer and Finance Director of a number UK listed public and private companies, including Alizyme plc and Peptide Therapeutics Group plc. Extensive experience in raising substantial amounts of equity capital, advising and working at Board level for a diverse range of companies internationally. Fellow of the Association of Chartered Certified Accountants. MBA from Cranfield School of Management.



<u>Dimitri F. Dimitriou, MSc</u> Chief Executive Officer

25 years' experience in the pharmaceutical and biotech industry. Co-founder of ImmuPharma. Former Senior Director, Worldwide Business Development at GlaxoSmithKline, focusing on worldwide corporate deals. 8 years at Procter & Gamble in marketing, R&D and business development positions. Began his career in marketing at Novartis (Sandoz). BSc in Biochemistry from Kings College and MSc in pathology from the Imperial College Medical School.



Dr Robert Zimmer, MD, PhD
President & Chief Scientific Officer

Founder of ImmuPharma. Expert in clinical pharmacology and life cycle management. Developed a substantial number of products already on the market. Formerly at Roche's headquarters as coordinator of clinical pharmacology and international clinical leader. Former Director and Head of R&D at SkyePharma. MD from Strasbourg Medical School and PhD from the University of Aix-Marseille (France).

### Management team



#### Dr Franco Di Muzio

#### Senior Non-Executive Director

40 years experience in the pharmaceutical and other industries, encompassing international management experience in business development, strategic marketing, international finance, M & A and re-engineering businesses. Formerly Executive Vice President of Bristol Myers Squibb's medical equipment and products division, Weck International Inc., in charge of Europe, Asia, Middle East and Africa. Ex Area Managing Director Head of all Glaxo Wellcome plc. business in the Middle East, Africa and Turkey. Ex Managing Director of Alza International. Formerly with Colgate Palmolive and Nestle.



Dr Stéphane Méry

#### Non-Executive Director

Extensive experience in the Healthcare industry. Currently CEO of Contronics Ltd. Former partner at Beringea LLP, a \$400m US/UK venture capital fund. Previously, Fund Manager/CEO of the Bloomsbury Bioseed Fund. Formerly Associate Director, Worldwide Business Development, for SmithKline Beecham (GSK) responsible for the negotiation of several major inlicense deals and acquisitions. Doctor in Veterinary Medicine, Veterinary Pathologist, specialising in Nasal Toxicology at the Chemical Industry Institute of Toxicology (CIIT) in North Carolina. MBA from INSEAD.



**Tracy Weimar** 

#### Vice President, Operations & Finance

Ex Director, Worldwide Business Development at GlaxoSmithKline, involved in a number of corporate licensing deals. A number of positions in health economics, strategy development, sales and marketing at GSK. Non-executive director for the Avon and Wiltshire Mental Health Partnership NHS Trust (member of Audit and Remuneration Committees of the Trust). 5 years at Arthur Andersen in San Francisco and London, responsible for a range of consulting and compliance projects. MBA from the London Business School and BA in Economics from the University of California, Berkeley, USA.

#### Team

Lisa Baderoon

Head of Public & Investor Relations

**Dr Paolo Bessieres** 

Vice President Head of Business Development

**Dr Fanny Valleix** 

Head of Clinical Research

**Dr Catherine Bernard** 

Head of Regulatory Affairs

**Claire Venin** 

Researcher

**Juliette Fremaux** 

Researcher

Sebastien Goudreau

**Research Director** 



Chair of Therapeutic Immunology at CNRS (Strasbourg)

**Dr Gilles Guichard** 

Research Director at CNRS (Bordeaux)

**Dr José Courty** 

Research Director at CNRS (Paris)





- The CNRS is the largest basic research organisation in Europe.
- It takes first place in the Nature Index, a new ranking of international scientific institutions proposed by the journal Nature. It is ahead of the Chinese Academy of Sciences, Germany's Max Planck Society and the Harvard University in the US.

ImmuPharma's Research Engine

### Lupuzor™ deal – case study



- In 2009, ImmuPharma licensed the world-wide rights to Lupuzor™ to US specialty pharma company Cephalon Inc.
- Cephalon paid ImmuPharma \$15m upfront prior to phase IIb completion and \$30m when phase IIb interim data became available
- This was part of \$500m cash milestone payments plus high royalties on sales
- Cephalon assumed all costs of development and commercialisation
- Cephalon acquired by Teva Pharmaceuticals (primarily a generics company) and ImmuPharma terminated the license deal regaining all product rights due to non-compete and change of control clauses

Provides validation and asset value



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