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ImmuPharma plc

# *Developing Innovative Peptides*

*October 2018*

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# Company summary

- Pharma development company listed on AIM since 2006 (LSE:IMM)
- Lead drug candidate, Lupuzor™, for the treatment of Lupus, a life threatening autoimmune disease
  - Phase III pivotal study recently announced top line data
  - Substantial 'blockbuster' market potential
- P140 platform with potential to target further autoimmune diseases
- 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 National de la Recherche Scientifique (CNRS)
  - Europe's largest research institution
- Experienced management and research team
- Low-cost business model based on outsourcing (c. 20 people)
- **Recent corporate update announced : 7 September 2018**
- **Interim results announced : 26 September 2018**

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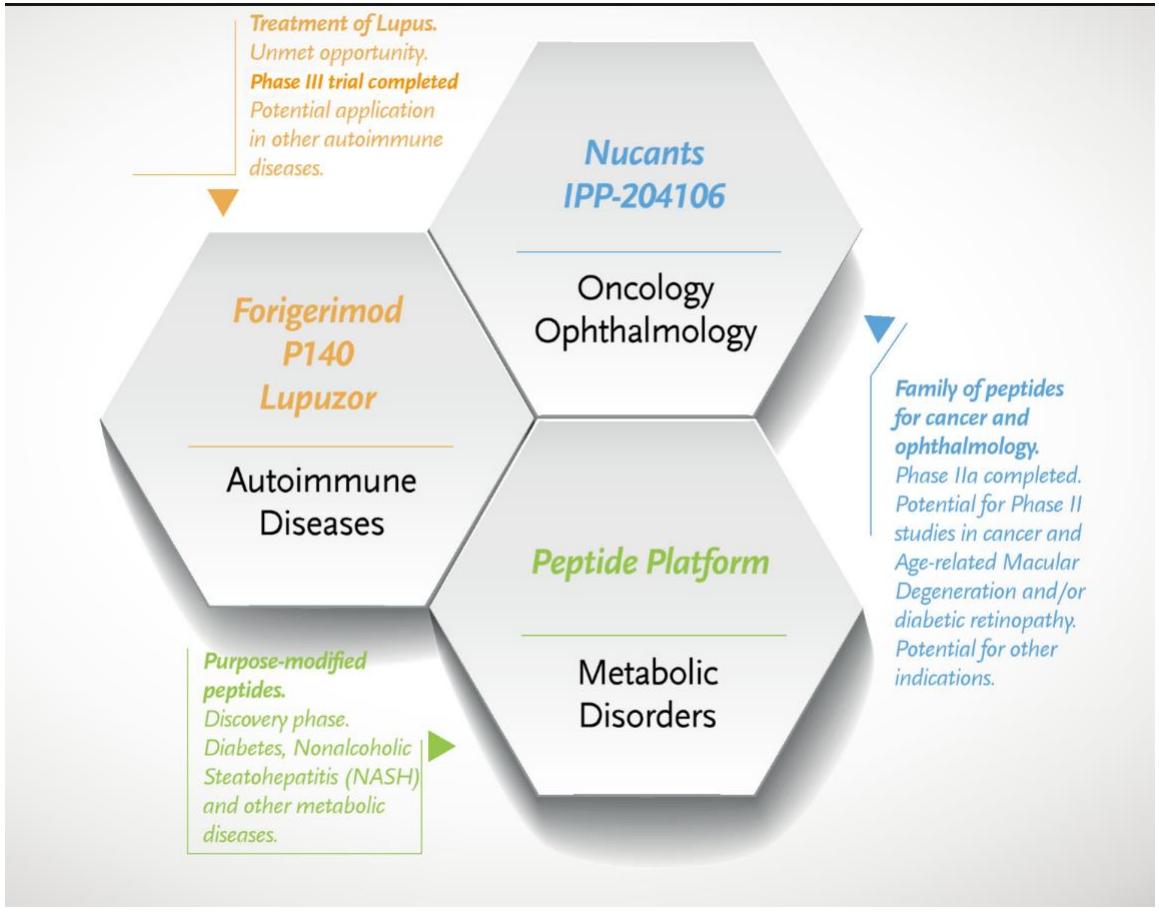
# Pipeline overview



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# Lupuzor™

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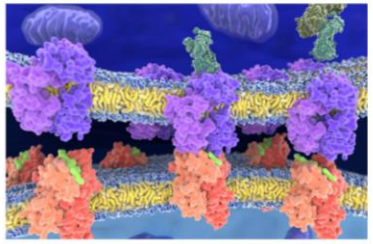

Significant evidence in support of Lupuzor™

SPA & Fast-Track designation for Lupuzor™

Phase III top line data recently announced

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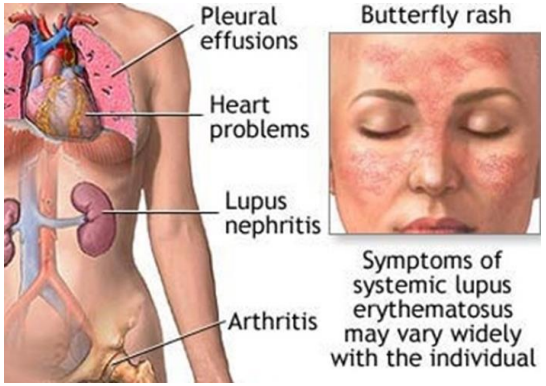
# What is Lupus?

- 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
- **ImmuPharma's Lupuzor™ has recently reported top line data from its pivotal Phase III trial which demonstrated its outstanding safety profile**




* source: Lupus Foundation of America 'www.lupus.org' (2017)

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# *Lupuzor™ key USP's*

- Novel mechanism that modulates (***not blocks***) the immune system
- Outstanding safety profile
- Attractive economics

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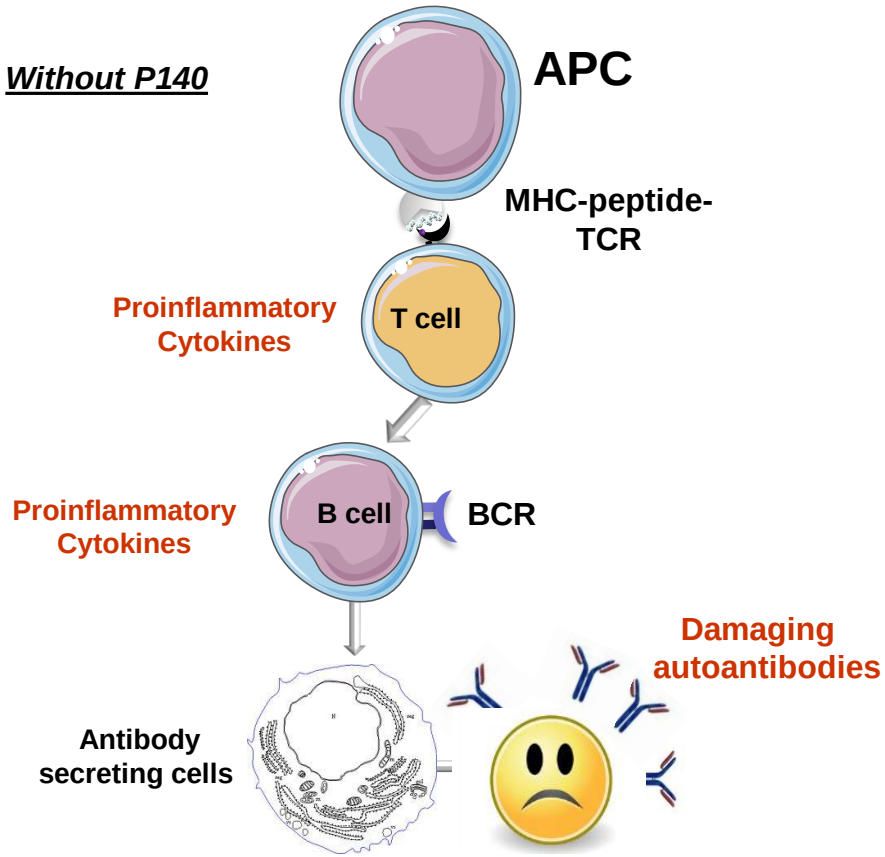
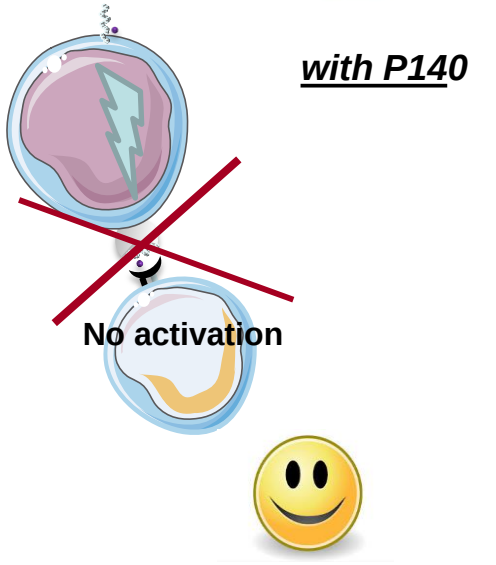
# Lupuzor™ - mechanism of action



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# *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$25,000 / per patient / per year
- Lupuzor™ 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)

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# *Lupuzor™ phase III trial*

- 28 investigator sites
    - 11 centres in the US
    - 16 centres in Europe
    - 1 centre in Mauritius
    - Simbec-Orion (CRO) experts in Lupus trials

SIMBEC ORION GROUP

- 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)

**Find more information on: www.ClinicalTrials.gov (Search: 'Lupuzor')**

ClinicalTrials.gov
A service of the U.S. National Institutes of Health

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# *Lupuzor™ top line data*

## *- announced 17 April 2018 & 29 May 2018*

- Lupuzor™ demonstrated a superior response rate over placebo (52.5% vs 44.6% "responders") in the primary analysis on the Full Analysis Set of all 202 patients
- Due to the high response rate in the placebo group, this superior response did not allow statistical significance to be reached ($p = 0.2631$) and the trial's primary end point was not met
- Across the whole study population, in those patients who had anti-dsDNA autoantibodies, Lupuzor™ demonstrated a superior response rate over placebo (61.5% vs 47.3%, $p = 0.0967$)
- Further data analysis demonstrated that in the Europe cohort (130 patients) Lupuzor™ plus standard of care showed statistically significant reductions in disease activity compared to placebo plus standard of care in 79 patients who were anti-dsDNA autoantibody positive (71.1% vs 48.8%, $p = 0.0218$)
- The study confirmed the outstanding safety profile of Lupuzor™, with no serious adverse events reported
- **Next steps for Lupuzor™**
  - Six month extension study
  - Managed Access Programme (MAP)

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# *Lupuzor™ phase III trial*
## *- six month extension study*

- ImmuPharma has initiated a six month "follow-up" study permitting eligible patients from the completed Phase III study, to receive Lupuzor™ (plus “Standard of Care”)
- Follows requests from both Investigators and patients involved in the Phase III study
- The extension study is an open-label scheme with results to be gathered as an “extension” open label study, independent of the pivotal Phase III trial
- 62 eligible patients have completed enrolment
- Study results available in Q2 2019

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# *Lupuzor™*

## *- Managed Access Programme ("MAP")*

- The key objectives of the MAP, based on the clinical and safety data received from the recently announced Phase III trial, are to promote the use of Lupuzor™ by allowing Lupus patients early access to Lupuzor™, whilst continuing to engage with Lupus specialists and practitioners
- This will allow Lupus patients ongoing access to Lupuzor™ prior to any regulatory filing
- Allows the collection of valuable data from these patients, adding significantly to the existing data package
- Up to 500 patients will be recruited for the MAP
- These patients will be granted access to Lupuzor™ for a minimum of two years, free of charge
- The programme will be funded from current cash resources

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# P140 platform
## - targeting major auto-immune disease indications

- ImmuPharma together with Professor Sylviane Muller, Lupuzor's inventor, have presented new evidence supporting Lupuzor's™ P140 peptide activity in several other major auto-immune disease indications outside of Lupus

Prof. Sylviane Muller

A shift in treating auto-immune disease

- Based on P140 strong efficacy and safety profile and mechanism of action
- This includes Rheumatoid Arthritis, Crohn's Disease, and Asthma - the peptide appears to have general effects against chronic inflammatory indications
- Other pre-clinical evidence supports the molecule's use in: Neuropsychiatric lupus (NPSLE); Gougerot-Sjögren syndrome (GSS); and Guillain-Barre disease (chronic/CIDP)
- Further preclinical work continues with Prof. Muller at the CNRS with the objective of further indications moving into the clinic in due course.

**For more information go to: http://www.immupharma.co.uk/media/events/**

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# Nucant Cancer Programme

## - clinical development collaboration with Incanthera

- 'Heads of Terms' signed with Incanthera Limited ("Incanthera"), a specialist oncology development company

Key highlights include:

- Incanthera will licence in and take up the continued clinical development of the Nucant cancer programme as an integral part of its own cancer development portfolio

- ImmuPharma has invested £2m into Incanthera by subscribing for 363,637 new ordinary Incanthera shares(16%) at a price of £5.50 per share valuing Incanthera at a pre-money valuation of approximately £10m

- Incanthera has a period of exclusivity until 31st Dec 2018, to finalise the terms of a 'Definitive Licence Agreement'

- These terms are expected to include:
  - Incanthera to pay a licence payment to ImmuPharma of £1m, via the issuance of new ordinary shares in Incanthera. – separate to the initial investment by ImmuPharma
  - Incanthera will be responsible for all of the development costs for the Nucant programme; and
  - All future commercialisation revenues will be shared equally between the two companies

- Incanthera is currently preparing for an IPO on AIM

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# *Ureka*

## *- divestment process*

- Ureka is ImmuPharma's wholly owned subsidiary, based in Bordeaux
- Research is focused on treatments for Type II diabetes and NASH (Non-Alcoholic-Steato-Hepatitis) has recently demonstrated success in recognised preclinical studies
- Following an extensive review, Ureka, whilst having exciting and innovative technologies, is not part of the ongoing strategy of ImmuPharma
- All opportunities to divest Ureka and now being considered
- With the divestment of Ureka, ImmuPhama will retain an interest in any future commercial success

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# *Investment rationale*

- Confident of Lupuzor™'s future as a blockbuster asset still 100% owned by ImmuPharma
- Competitive efficacy & safety profile
- MAP programme provides patients with early access to Lupuzor™
- P140 platform has potential to expand into other autoimmune diseases

- Nucant collaboration agreement with Incanthera provides effective route to fast track development pathway with cancer development specialist
- Ureka divestment allows for focus on late stage assets whilst retaining interest in future success

- Robust financial position balance: £9.0m (H1 2018)
- Continued transparency with news-flow
- Proactive IR strategy ongoing

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