



RNS | 13 APRIL 2022

## ImmuPharma PLC

("ImmuPharma" or the "Company")

### **UPDATE on P140 (LUPUZOR™) clinical progress Data confirms positive readout from P140 PK study**

ImmuPharma PLC (LSE:IMM), the specialist drug discovery and development company, is delighted to provide positive data from the Lupuzor™/P140 pharmacokinetic ("PK") study, required by the US Food & Drug Administration ("FDA"), as part of the new optimised international Phase 3 trial of Lupuzor™ in lupus patients.

#### **Key highlights**

- Data successfully demonstrates the PK study has met the key endpoints requested by the FDA
- The dosing of healthy subjects commenced on 15 February 2022 following approval by the Medicines and Healthcare products Regulatory Agency ("MHRA")
- Subcutaneous injection of P140 (in both 200 microgram ("mcg") and 800 mcg doses (note: 1mcg = 1 millionth of a gram) showed a clear time and dose-related PK profile which is detectable in the blood of human volunteers and applicable for all potential clinical dosing regimens of P140
- The final group of subjects completed dosing on 30 March 2022. This was a group of subjects that received an intravenous injection of a 800 mcg dose of P140, which showed successful measurement of the absolute bioavailability of the drug (as a control)
- Importantly, and in-line with all human dosing to date, P140 was safe and well tolerated across all doses and in all subjects
- This positive PK data now clears the path for commencement of all clinical studies within the P140 platform. In addition to lupus, there is a planned Phase 2a/3 pivotal trial in chronic inflammatory demyelinating polyneuropathy ("CIDP")
- Avion Pharmaceuticals, our US partner, has been integral to the development, initiation and successful conclusion of this PK study. Together, we are preparing next steps for the progression of the P140 clinical program and this will be communicated in due course

#### **Commenting on the announcement, Tim McCarthy, Chief Executive Officer, said:**

*"We are delighted to be announcing this successful readout of the PK study. This is a significant milestone for ImmuPharma and for shareholders, and recognition of the key investment thesis behind*

*ImmuPharma, in respect to having P140 (Lupuzor™), a late-stage Phase 3 clinical asset for the treatment of lupus patients with a Phase 2a/3 pivotal trial in CIDP close behind.”*

**Dr Tim Franklin, Chief Operating Officer, added:**

*“The PK results are highly significant for the progress of the P140 program. The ImmuPharma Biotech team in Bordeaux also performed predictive modelling in animals that not only confirmed our confidence to detect P140 in the human PK study, but also proved, in those models, that P140 continues to work long after it disappears from the plasma. This strongly supports the unique autophagy mechanism of action shown by Prof. Sylviane Muller. We would like to extend our thanks to Prof Muller and our longstanding collaboration partner, CNRS. We look forward, to working closely with our partner, Avion, on the next steps towards the Phase 3 study of Lupuzor™ in lupus patients, whilst we also progress our CIDP clinical program.”*

End

*This announcement contains inside information as stipulated under the UK version of the Market Abuse Regulation no 596/2014 which is part of English law by virtue of the European (withdrawal) Act 2018, as amended. On publication of this announcement via a regulatory information service, this information is considered to be in the public domain.*

For further information please contact:

**ImmuPharma PLC ([www.immupharma.com](http://www.immupharma.com))**

+ 44 (0) 207 206 2650

Tim McCarthy, Chairman and Chief Executive Officer

Dr Tim Franklin, Chief Operating Officer

Lisa Baderoon, Head of Investor Relations & Non-Executive Director

+ 44 (0) 7721 413496

**SPARK Advisory Partners Limited (NOMAD)**

+44 (0) 203 368 3550

Neil Baldwin

**Stanford Capital Partners (Joint Broker)**

+44 (0) 20 3650 3650

Patrick Claridge

John Howes

Bob Pountney

**SI Capital (Joint Broker)**

+44 (0) 1483 413500

Nick Emerson

**Notes to Editors**

**About ImmuPharma PLC**

ImmuPharma PLC (LSE AIM: IMM) is a specialty biopharmaceutical company that discovers and develops peptide-based therapeutics. The Company's portfolio includes novel peptide therapeutics for autoimmune diseases, metabolic diseases, anti-infectives and cancer. The lead program, Lupuzor™, is a first-in class autophagy immunomodulator which is in Phase 3 for the treatment of lupus and preclinical analysis suggest therapeutic activity for many other autoimmune diseases that share the same autophagy mechanism of action. ImmuPharma and Avion Pharmaceuticals signed on 28 November 2019, an exclusive licence and development agreement and trademark agreement for Lupuzor™ to fund a new international Phase 3 trial for Lupuzor™ and commercialise in the US.

For additional information about ImmuPharma please visit [www.immupharma.co.uk](http://www.immupharma.co.uk)

ImmuPharma's LEI (Legal Entity Identifier) code: 213800VZKGHXC7VUS895.

**About Lupus (Systemic Lupus Erythematosus / SLE)**

Lupus is a chronic inflammatory disease which is thought to affect some 5 million individuals worldwide. The current standard of care still consists of drugs which have many side-effects and limited efficacy. Despite the need for an effective treatment, only two therapies, namely GlaxoSmithKline's Benlysta and more recently, Astra Zeneca's Saphnelo, have been approved to treat the condition over the past 50 years. As such, there clearly exists an unmet medical need for a drug that has a strong efficacy and safety profile.

**About MHRA**

The Medicines and Healthcare products Regulatory Agency ("MHRA") is an executive agency of the Department of Health and Social Care in the United Kingdom which is responsible for ensuring that medicines and medical devices work and are acceptably safe. For more information go to:

<https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency>