



19<sup>th</sup> April 2023

**ImmuPharma PLC**  
("ImmuPharma" or the "Company")

**FDA confirms Type-C meeting date of 7th June 2023  
for Phase 2/3 adaptive study of Lupuzor™ in lupus**

ImmuPharma PLC (LSE:IMM), the specialist drug discovery and development company, is pleased to announce that the Food and Drug Administration ("FDA") has set a date of 7<sup>th</sup> June 2023 for a Type-C meeting to provide guidance on the Phase 2/3 adaptive study of Lupuzor™ ("P140") in patients with systemic lupus erythematosus ("SLE/Lupus"). This follows on from the recent announcement on 27 March 2023.

Avion (our US partner) has provided the FDA with a full package of documents and information which addresses all the key guidance points from the previous Type-C meeting, particularly concerning dosing. The FDA guidance is in addition to the clinical pharmacokinetic ("PK") study completed last year which provided, amongst other observations, a critical insight into the relevant dose range and method of administration of Lupuzor™ (P140). This Phase 2/3 study remains on track to commence in H2 2023.

**Commenting on the announcement, Tim McCarthy, CEO of ImmuPharma, said:**

*"Following on from our announcement last week of the pre-IND meeting with the FDA on P140 in CIDP, we are delighted to confirm this meeting date with the FDA on P140 in lupus. With the prospect of both of these indications moving positively forward into pivotal studies in H2 2023 there is real value momentum building in our P140 franchise"*

*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.*

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## **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 and anti-infectives. The lead program, P140 (Lupuzor™), is a first-in class autophagy immunomodulator for the treatment of Lupus and preclinical analysis suggest therapeutic activity for many other autoimmune diseases that share the same autophagy mechanism of action.

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

### **About Avion Pharmaceuticals LLC**

Avion Pharmaceuticals, LLC, is a specialty pharmaceutical company formed to develop, acquire and market a portfolio of innovative pharmaceutical products in the Women's Health and other therapeutic categories aligned with its mission to improve the quality of patient lives. Avion Pharmaceuticals focuses on identifying opportunities to develop, acquire and enhance the market potential of innovative, commercially available therapeutics and late-stage development drugs to fulfil unmet medical needs.

For more information, visit [www.avionrx.com](http://www.avionrx.com).

### **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 steroid and anti-malarial therapies which many have side-effects and poor response in many patients. Recently more targeted monoclonal therapies are GlaxoSmithKline's Benlysta and more recently, AstraZeneca's Saphnelo. There still exists a high unmet medical need for a drug that has a strong efficacy and safety profile.

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