

19 June 2023

#### ImmuPharma PLC

("ImmuPharma" or the "Company")

# Phase 2/3 adaptive clinical trial of P140 (Lupuzor™) in Lupus to commence following FDA meeting

ImmuPharma PLC (LSE:IMM), the specialist drug discovery and development company, is pleased to announce that the Phase 2/3 adaptive clinical trial of P140 (Lupuzor™) in patients with systemic lupus erythematosus ("SLE/Lupus") is to commence in H2 2023.

### Key highlights:

- Following the receipt of comprehensive guidance from the Food and Drug Administration ("FDA") in 3 separate Type-C meetings, a Phase 2/3 adaptive clinical trial of P140 (Lupuzor™) in patients with Lupus will commence in H2 2023.
- Avion Pharmaceuticals ("Avion") have confirmed that under the previously announced terms of the existing Licence Agreement, they will continue to support the new clinical trial design and Avion and ImmuPharma have agreed to proceed and will now begin preparatory steps for the Phase 2/3 adaptive clinical trial.
- The trial design and protocol is substantially different from previous clinical trials that ImmuPharma has completed and includes maintaining subcutaneous dosing but at much higher concentrations and significant changes to patient inclusion criteria and primary and secondary clinical endpoints.

The detailed protocol and key elements of the clinical trial design will be communicated at a later stage once the details of the trial are available on clinicaltrials.gov (a comprehensive database of privately and publicly funded clinical studies conducted around the world).

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

"We are delighted to be moving forward with the study for P140 (Lupuzor™) in Lupus after receiving comprehensive guidance from the FDA on the protocol. Avion and ourselves are confident in the new design of the Phase 2/3 adaptive clinical trial and in ultimately delivering a new efficacious and safe therapy for Lupus patients."

# Commenting further, Art Deas, CEO of Avion said:

"The FDA has provided us with comprehensive guidance to commence the Phase 2/3 adaptive clinical trial for P140 (Lupuzor™) and we look forward to continue working closely with ImmuPharma to deliver a successful result for Lupus patients."

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

#### **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.

#### 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.