



07 July 2022

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

FDA confirms response date for Type C Meeting as 29th August 2022

ImmuPharma PLC (LSE:IMM), the specialist drug discovery and development company, is delighted to announce that its US partner for Lupuzor™ (P140), Avion Pharmaceuticals ("Avion"), has advised that it has now received Type C Meeting confirmation from the Food and Drug Administration ("FDA").

The statement of purpose, objectives, and proposed agenda of the Type C meeting have been agreed with the FDA. The FDA also agree that written responses to the agenda items would be the most appropriate means for responding and that a face to face meeting is not required. The agreed date from the FDA for providing its written responses is 29 August 2022.

As per our announcement of 27 June 2022, Avion recently requested a Type C Meeting, primarily to report the data on the successfully completed P140 pharmacokinetic ("PK") study. In addition, Avion has taken the opportunity to ask questions related to the use of P140. This aims to strengthen the future product label and secure advantageous differentiation of P140 for use in Lupus patients.

As noted in previous announcements, the PK study required by the FDA met all the key endpoints and in-line with all human dosing to date, P140 was safe and well tolerated across all doses and in all subjects.

As reported from the previous phase 3 trial, patients who were biomarker positive (anti-ds DNA antibody positive) responded better to Lupuzor™ than those who were biomarker negative. However, in the previous study patients were not screened and selected on the basis of biomarker positivity prior to randomisation. The biomarker will act as a very useful "theragnostic" to ensure that Lupus patients who show this biomarker have the best opportunity to receive the maximum benefit from Lupuzor™ therapy. The new international Phase 3 clinical trial protocol requires the presence of the biomarker before being allowed into the study. This protocol was accepted by the FDA at the previous Type C meeting in 2021.

Commenting on the announcement, Tim McCarthy, Chief Executive Officer, said: *"We applaud the quick turnaround from the FDA in respect to Avion's request for this Type C Meeting and pleased to note the FDA's confirmation that only a written response is required and no face to face meeting is needed."*

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, 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.

The new international Phase 3 trial for Lupuzor™ is being funded by Avion, who have the exclusive rights to commercialise Lupuzor™ in the US. The rest of the world rights remain with ImmuPharma and partnering discussions will be an integral part of creating further opportunities for Lupuzor™ in Lupus and the P140 platform across several additional indication targets going forward. The next indication being Chronic inflammatory demyelinating polyneuropathy (CIDP)

For additional information about ImmuPharma please visit 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.