



RNS: RELEASE

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

**Avion seeks final regulatory guidance as it prepares for the start of the international Phase 3 trial of Lupuzor™ in Lupus patients**

ImmuPharma PLC (LSE:IMM), the specialist drug discovery and development company, is delighted to announce that, having met all the Food and Drug Administration's ("FDA") requirements, Avion Pharmaceuticals ("Avion"), its US partner, has confirmed that it has sought final regulatory guidance from the FDA, as it actively prepares for the start of the international Phase 3 trial of Lupuzor™ in Lupus patients.

This confirmation follows a recent meeting between the two companies at Avion's US headquarters in Atlanta, Georgia.

Further to our last update on 4<sup>th</sup> May 2022, Avion has submitted, via a Type C Meeting, the positive results from the Lupuzor™/P140 Pharmacokinetic ("PK") study to the FDA.

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), demonstrated that P140 was safe and well tolerated across all doses and in all subjects.

As previously disclosed, as an integral part of the licence and development agreement for Lupuzor™ entered into between Avion and ImmuPharma, the new international Phase 3 trial for Lupuzor™ is being funded by Avion, who have the exclusive rights to commercialise Lupuzor™ in the US, whilst the rest of the world rights remain with ImmuPharma.

**Commenting on the announcement, Tim McCarthy, Chief Executive Officer, said:** *"This final step by Avion is a pivotal moment for the Company and for the progress of Lupuzor™ towards becoming a groundbreaking new treatment for Lupus patients. Lupuzor's™ unique mechanism of action and robust safety profile will, we believe, position Lupuzor™ as a first line therapy to many Lupus sufferers globally."*

**Art Deas, Chief Executive Officer of Avion further commented:** *"Having met all the FDA's requirements, we are delighted to be seeking the FDA's final guidance on moving Lupuzor™ forward into the new international Phase 3 trial. We anticipate Lupuzor™ becoming the leading product in our portfolio and that it will be instrumental in bringing an innovative treatment to Lupus patients, which is not currently available on the market today."*

*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 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.

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.