



RNS | 7 FEBRUARY 2022

**ImmuPharma PLC**

("ImmuPharma" or the "Company")

**LUPUZOR™ UPDATE**

**PK study commencement approved by MHRA – patient dosing to commence imminently**

ImmuPharma PLC (LSE:IMM), the specialist drug discovery and development company, is delighted to provide an update on the Lupuzor™ pharmacokinetic ("PK") study, as part of the new optimised international Phase 3 trial of Lupuzor™ in Lupus patients.

**Key highlights**

- Medical and Health Products Regulatory Agency ("MHRA") approves commencement of the PK study
- Volunteers have been selected and approved for inclusion in the PK study
- Volunteer dosing to commence on 15 February 2022
- Study on track to deliver results around the end Q1 2022

Following the approval from the US Food & Drug Administration ("FDA") of the protocol for the pharmacokinetic ("PK") study and local Ethics committee approval, ImmuPharma has been working with Avion Pharmaceuticals ("Avion"), our exclusive US partner, and our Contract Research Organisation ("CRO"), Simbec-Orion, together with additional specialist service providers, to prepare the commencement of the study.

As part of the regulatory process, the Investigational Medicinal Product Dossier ("IMPd") required significant revision, due to the inclusion of a new proprietary synthesis of P140, which consequently affords greater IP protection and lower cost of goods. The new IMPd was submitted to the MHRA and, following a full review, the MHRA has approved the commencement of the PK study.

The PK study is a Phase I study to assess the presence of Lupuzor™ in the body after administration of a single dose. The study will be carried out in a total of up to 24 healthy male volunteers.

Volunteers have been selected and approved with dosing to commence on 15 February 2022. As previously advised, we expect study results to be available around the end of Q1 2022.

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

*"We are extremely pleased to see this next positive step for Lupuzor™, with approval from the MHRA to commence the PK study. We look forward to moving Lupuzor™ forward into the optimised Phase 3 study, in collaboration with our partner Avion, on the successful completion of the PK study. The study is on track to deliver results around the end of Q1 2022."*

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

*"The ImmuPharma Biotech team in Bordeaux and I are looking forward to the near-term completion of the PK study. Our CRO, Simbec-Orion, and other key collaborators including Prof. Sylviane Muller, have provided invaluable contribution in completing a robust and improved IMPd to the MHRA. We*

*look forward with Avion to moving Lupuzor™ forward and in parallel, we will continue to focus on unlocking further value through the other indications within the P140 platform and the anti-infective programs.”*

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:

<b>ImmuPharma PLC</b> ( <a href="http://www.immupharma.com">www.immupharma.com</a> )	+ 44 (0) 207 152 4080
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
<b>SPARK Advisory Partners Limited (NOMAD)</b>	+44 (0) 203 368 3550
Neil Baldwin	
<b>Stanford Capital Partners (Joint Broker)</b>	+44 (0) 20 3650 3650
Patrick Claridge	
John Howes	
Bob Pountney	
<b>SI Capital (Joint Broker)</b>	+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 Simbec-Orion

Simbec-Orion, for the last four decades, has been providing clinical trial management services across a wide range of therapeutic indications and phases. The clinical research organisation with a flexible, specialist approach, they strive to become a trusted partner for their clients. Their passion as a CRO is rare diseases and oncology.

Responding to the evolving needs of its clients has made them the contract research organisation they are today. Offering a full-service clinical development portfolio, but with the size, agility, and structure to respond rapidly when needed. With a team of experienced management, clinical research and scientific advisory specialists, they deliver precise clinical research with expertise.

From Phase I clinical pharmacology studies through to Phase III rescue studies, central laboratory services, and post-marketing, they are the CRO ready to take on the challenge – whatever the indication or compound you are passionate about, wherever you are in your clinical development journey. They will manage every element of your clinical development, so you can focus on the science. For more information go to:

[www.simbecorion.com](http://www.simbecorion.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 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>