



12 August 2021

ImmuPharma PLC

("ImmuPharma" or the "Company")

FDA approves the Lupuzor™ PK study

ImmuPharma PLC (LSE:IMM) (Euronext Growth Brussels: ALIMM), the specialist drug discovery and development company, is delighted to announce that the US Food & Drug Administration ("FDA") has approved the commencement of the pharmacokinetic ("PK") study, as part of the new optimised international Phase 3 trial of Lupuzor™.

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 subjects.

Dependent on timing of patient recruitment, we anticipate that the PK study will take between 8-12 weeks to complete, from commencement.

Preparations will be made to commence the Phase 3 study, following completion of the PK study. For the continued late-stage program development, ImmuPharma and Avion Pharmaceuticals LLC ("Avion"), as part of a joint steering committee, agreed on a collaborative group consisting of a Board of Key Opinion Leaders ("KOLs") and a leading medical patient advocacy group. Collectively, this network, due to its in-depth knowledge of the lupus disease and their access to lupus patient groups, will be invaluable to the successful outcome of the Phase 3 trial.

ImmuPharma will provide an update on the progress of the PK study once it has commenced.

Commenting on the announcement, Tim McCarthy, Chairman & CEO of ImmuPharma said: *"We are extremely pleased to see the next positive steps for Lupuzor™, with continued positive dialogue with the FDA, their approval to commence the PK study and an agreed clinical and regulatory pathway over the next period. We look forward to providing further progress updates on the PK study and ultimately moving Lupuzor™ forward into the optimised Phase 3 study, on the successful completion of the PK study."*

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.

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Notes to Editors

About ImmuPharma PLC

ImmuPharma PLC (LSE AIM: IMM – Euronext Growth: ALIMM) 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

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

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 drugs which have many side-effects and limited efficacy. Despite the need for an effective treatment, only one new therapy, namely GlaxoSmithKline's Benlysta, has 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.