

9 February 2021

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

### **Lupuzor™ scheduled to commence international Phase 3 trial in Lupus patients in H2 2021**

ImmuPharma PLC (LSE:IMM) (Euronext Growth Brussels: ALIMM), the specialist drug discovery and development company, announces an update in respect to the new optimised international Phase 3 trial of Lupuzor™ in systemic lupus erythematosus ("SLE"), a potentially life-threatening auto-immune disease.

As indicated in the 20 November 2020 announcement, Avion Pharmaceuticals ("Avion"), ImmuPharma's licensing partner for Lupuzor™, met with the US Food & Drug Administration ("FDA") on 4 December 2020 for a Type 'A' Meeting Request.

Avion has received feedback from the FDA, and has now advised ImmuPharma of the programme of activities in respect to its commitment to schedule next steps.

In response to the FDA input, Avion, in partnership with ImmuPharma, has plans to develop and validate a bioanalytical assay, to confirm the clinical pharmacology and pharmacokinetic ("PK") characterizations of Lupuzor™, prior to commencement of the Phase 3 trial.

A final guidance meeting between Avion and the FDA is being planned at which Avion will submit the methodology for assessing PK as part of the Phase 3 trial. This meeting, which is expected to take place in Q2, will also confirm previous submissions to FDA on the study design, clinical end points and approval process.

As indicated in the 20 November 2020 announcement, ImmuPharma initiated the production of a new batch of Lupuzor™ clinical trial material specifically for the Phase 3 trial and it can be confirmed that this will be ready for the start of the trial.

As part of the FDA feedback from the meeting on 4 December 2020, it has been clarified that a Special Protocol Assessment ("SPA") will not be applicable and a conditional approval of Lupuzor™, whilst the Phase 3 trial is underway, has not been confirmed at this time.

#### **Commenting on the announcement, Dimitri Dimitriou, CEO of ImmuPharma said:**

*"We are extremely pleased to see the positive progress of Lupuzor™ towards the commencement of the international Phase 3 trial with Avion. We will continue to work closely with Avion over the next period to ensure the start of the Phase 3 study remains on schedule for H2 2021."*

**Art Deas, Chief Executive Officer, Avion Pharmaceuticals added:** *"Following continued positive dialogue with the FDA and with an agreed clinical and regulatory pathway over the next period, we look forward to moving Lupuzor™ ahead later this year."*

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](http://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](http://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.