# FDA to agree on the Lupzuor™ PK study via a written response to “Type C” meeting as Avion prepares for international Phase 3 trial

ImmuPharma PLC (LSE:IMM) (Euronext Growth Brussels: ALIMM), the specialist drug discovery and development company, announces that its US Lupuzor™ partner, Avion Pharmaceuticals (“Avion”) has received a positive response from the US Food & Drug Administration (“FDA”) for a “Type C” meeting. The FDA has advised that they do not require a formal face to face meeting and will provide their written response to Avion approximately by the end of July 2021.

As noted in our previous announcement of 9 February, this is the final guidance meeting at which the FDA will review the proposed methodology of the pharmacokinetic (“PK”) study. This study was requested by the FDA as part of the new optimised international Phase 3 trial of Lupuzor™ in systemic lupus erythematosus (“SLE”), a potentially life-threatening autoimmune disease.

ImmuPharma will provide an update as soon as Avion has received the written response from the FDA and advised ImmuPharma of the next steps and timetable towards commencing the Phase 3 trial this year.

Commenting on the announcement, Tim Franklin, COO of ImmuPharma said: *“We continue to acknowledge the FDA’s support following constructive meetings and feedback this year with our partner Avion. ImmuPharma and Avion are fully committed to commencing the Lupuzor™ Phase 3 trial in Lupus patients this year. Again, we reiterate Lupuzor’s™ unique mechanism of action and robust safety profile to date, which we believe will position Lupuzor™ as a first line therapy to many Lupus sufferers globally.”*

**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:

**ImmuPharma PLC (www.immupharma.com)** + 44 (0) 207 152 4080
Tim McCarthy, Chairman
Dimitri Dimitriou, Chief Executive Officer
Lisa Baderoon, Head of Investor Relations + 44 (0) 7721 413496

## Press contacts:

**Gunther De Backer** Partner, Backstage Communication

- gunther@backstagecom.be
- +32475903909
- BackstageCommunicationSPRL
- backstagecom.be

**Olivier Duquaine** Managing Director, Backstage Communication

- olivier@backstagecom.be
- +32477504784
- BackstageCommunicationSPRL