## ImmuPharma plc

("ImmuPharma" or the "Company")

## Submission to the FDA for a Special Protocol Assessment (SPA) for the forthcoming international Phase III trial of Lupuzor™ in Lupus Patients

ImmuPharma plc (LSE:IMM) (Euronext Growth Brussels: ALIMM), the specialist drug discovery and development company, announces an important regulatory milestone in preparation for the new optimised international Phase III trial of Lupuzor™ for systemic lupus erythematosus ("SLE") a potentially life-threatening auto-immune disease.

ImmuPharma's licensing partner for Lupuzor™, Avion Pharmaceuticals LLC ("Avion"), has submitted a Special Protocol Assessment ("SPA") request to the US Food & Drug Administration ("FDA"). SPA is a process in which sponsors reach agreement with the FDA on the design and size of clinical trials such that they adequately address scientific and regulatory requirements for a study that could support marketing approval. The previous Phase III clinical trial of Lupuzor™ in SLE was also carried out under ImmuPharma's SPA. The review period for an SPA request is up to 45 days.

On 28 November 2019, ImmuPharma and Avion signed an exclusive licence and development agreement and trademark agreement for Lupuzor™, with Avion agreeing to fund a new international Phase III trial and commercialising Lupuzor™ in the US. Since then, both companies have been working closely on the clinical trial design and strategy, bolstered by consultation with an eminent group of key opinion leaders. This tripartite Phase III protocol development approach provided thorough and detailed support for developing the most relevant clinical trial for Lupuzor™ in SLE patients. Data and results from the first Phase III clinical study were analysed and considered in detail and, as a result, a new optimised international Phase III study protocol has been finalised and is now the subject of the SPA request to FDA.

The new Phase III study design will be communicated to the market at a later date, once agreed with the FDA, and in due course will appear on 'clinicaltrials.gov'.

This announcement contains inside information for the purposes of Article 7 of Regulation (EU) 596/2014. ("MAR")

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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 consists of four novel peptide therapy areas which are: Autoimmunity, Metabolism, Cancer and Anti-Infectives. The lead program, Lupuzor™, is a first-in class autophagy immunomodulator which is in Phase III 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 29 November 2019, an exclusive licence and development agreement and trademark agreement for Lupuzor™ to fund a new international Phase III trial for Lupuzor™ and commercialise in the US. For additional information about ImmuPharma please visit www.immupharma.com. ImmuPharma's LEI (Legal Entity Identifier) code: 213800VZKGHXC7VUS895.