**27 July 2020**

**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 includes novel peptide therapeutics for autoimmune diseases, metabolic diseases and cancer. The lead program, Lupuzor™, is a first-in class autophagy immunomodulator which is in Phase III for the treatment of systemic lupus erythematosus (lupus / SLE). Lupus is an autoimmune disease which if left untreated can be fatal. 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 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.

**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.

**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.

**Special Protocol Assessment (SPA)**

SPA is a process in which sponsors – in this case, Avion, may ask to meet with the FDA to reach agreement on the design and size of certain clinical trials to determine if they adequately address scientific and regulatory requirements for a study that could support marketing approval. An SPA agreement indicates concurrence by the FDA with the adequacy and acceptability of specific critical elements of overall protocol design (e.g., entry criteria, dose selection, endpoints, and planned analyses) for a study intended to support a future marketing application. These elements are critical to ensuring that the trial conducted under the protocol can be considered an adequate and well-controlled study that can support marketing approval. Feedback on these issues provides the greatest benefit to sponsors in planning late-phase development strategy. (Source: https://www.fda.gov/media/97618/download).