10 November 2020

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

Update on submission to the FDA for the forthcoming international Phase 3 trial of Lupuzor™ in Lupus patients

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

Key highlights:

- The FDA has offered to accept submission for a Type 'A' Meeting Request;
- Guidance to be sought by Avion on the new Phase 3 clinical trial;
- FDA also asked to consider a conditional approval of Lupuzor™, whilst Phase 3 trial underway; and
- Production of new Lupuzor™ Phase 3 clinical trial material has been initiated.

Following the notification by ImmuPharma, on 27 July 2020, that Avion Pharmaceuticals ("Avion"), ImmuPharma's licensing partner for Lupuzor™ had submitted a Special Protocol Assessment ("SPA") request to the US Food & Drug Administration ("FDA") for the new optimised international Phase 3 study, the FDA has now responded.

The FDA offered to accept submission for a Type 'A' Meeting Request, following which, Avion submitted a full dossier on 6 November 2020 through the FDA Type 'A' route which, in normal circumstances, leads to a guidance meeting within 30 days. However, FDA timeframes cannot be guaranteed. The guidance meeting will address the key aspects of the study design, clinical end points and approval process.

In addition, Avion has asked the FDA to consider a conditional approval while the new Phase 3 is underway. A conditional approval, which would allow the marketing of Lupuzor™ prior to the completion of the new Phase 3, would be based on the clinically significant data previously generated in the completed Phase 2 and 3 clinical trials to date. Lupuzor™ is extremely safe and well tolerated, and so, whilst the Directors believe that a successful consideration is only a potential possibility, it allows this to be asked.

In anticipation of the start of the new Phase 3 clinical trial, ImmuPharma has initiated the production of a new batch of the Lupuzor™ drug specifically for the trial.

ImmuPharma will provide an update as soon as Avion has met with the FDA and notified ImmuPharma of the outcome.

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

"ImmuPharma and Avion are appreciative of the FDA's fair treatment of Lupuzor™'s regulatory filing under these unprecedented times due to the Covid-19 pandemic, which has put immeasurable pressure on the FDA and the industry as a whole.

"Working closely with the team at Avion we are also encouraged by their confidence in Lupuzor™ illustrated by asking FDA to consider a conditional approval of Lupuzor™ in Lupus patients, prior to completion of the new Phase 3 clinical trial. Whilst we accept that a successful consideration is only a potential possibility, on the basis that Lupuzor™ has demonstrated a robust safety profile, it certainly allows this to be asked. We look forward to providing further updates in due course."

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, 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.