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

Avion submits clinical protocol of Phase 2/3 adaptive study of Lupuzor™ in lupus to FDA

ImmuPharma PLC (LSE:IMM), the specialist drug discovery and development company, is delighted to update the market on the next positive step in its Lupuzor™ (P140) program in patients with systemic lupus erythematosus ("SLE/Lupus"). This follows on from the recent announcement on 6 February 2023.

Key highlights:

- Avion Pharmaceuticals ("Avion") and ImmuPharma agreed in February on a Phase 2/3 adaptive trial design for the next clinical study of Lupuzor™ in Lupus patients.
- A Phase 2/3 clinical trial protocol has now been submitted to the Food and Drug Administration ("FDA"). This new design takes into account the FDA's key guidance points from the previous Type-C meeting in addition to insights from the pharmacokinetic ("PK") study completed last year.
- The submitted protocol contains many changes from the design of the previous Phase 3 clinical trial carried out by ImmuPharma. The most significant and important changes concern the level of dose being administered and the method of administration.
- A Type C meeting with the FDA has been requested and the date of the meeting should be confirmed within the FDA guidelines of 21 days from submission which is expected to be within the FDA guidelines of 75 days from submission. We will update the market with the date of the meeting once confirmed by FDA.
- The Phase 2/3 study remains on track to commence in H2 2023.

On 6 February 2023, ImmuPharma confirmed that they had agreed with Avion on an adaptive Phase 2/3 study for Lupuzor™ in SLE patients. For background, this is a one-protocol pivotal study which allows exploration of a dose-range in the Phase 2 part of the study, followed by seamless progression into the Phase 3 part of the study at the chosen dose. The overall timelines are much shorter than carrying out two separate protocols (i.e. Phase 2 followed by Phase 3). It is also expected to be less costly overall.

This new study design incorporates guidance from the FDA which advised exploration of higher dose levels than have been used in the clinical program to date, and insights gained from data generated from the PK study completed last year.

Consequently, it is expected that the Phase 2 part of the new clinical trial will identify a multiple times higher dose level to be used in the Phase 3 part compared to the 200mcg dose given to patients in the previous Phase 3 clinical trial carried out by ImmuPharma. Also it is proposed that the method of administration will be changed from a subcutaneous injection to an intravenous injection, so ensuring that significantly higher blood levels of Lupuzor™ (P140) can be achieved, thereby greatly increasing the probability of a significant efficacy result in patients.

Importantly, a clean safety profile of Lupuzor™ has already been established at the higher doses to be examined in the Phase 2 part, thereby preserving the Target Product Profile of Lupuzor™ which is to be significantly efficacious for patients with no serious side effects.

Commenting on the announcement, Tim McCarthy, CEO of ImmuPharma, said:

"We are extremely pleased to be moving positively forward with the Lupuzor™ program. Avion and ourselves believe that the new design of the Phase 2/3 adaptive study offers the greatest probability of a successful result for the overall benefit of Lupus patients. We remain on track to commence the trial in H2 2023."

Commenting further, Art Deas, CEO of Avion said:

"We remain committed to our full support of ImmuPharma, and with insights gained from last year's PK study and invaluable guidance from the FDA, we believe we have submitted the most robust clinical protocol for Lupuzor™."

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) is a specialty biopharmaceutical company that discovers and develops peptide-based therapeutics. The Company's portfolio includes novel peptide therapeutics for autoimmune diseases and anti-infectives. The lead program, P140 (Lupuzor™), is a first-in class autophagy immunomodulator for the treatment of Lupus and preclinical analysis suggest therapeutic activity for many other autoimmune diseases that share the same autophagy mechanism of action.

For additional information about ImmuPharma please visit www.immupharma.co.uk

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.

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 steroid and anti-malarial therapies which many have side-effects and poor response in many patients. Recently more targeted monoclonal therapies are GlaxoSmithKline's Benlysta and more recently, AstraZeneca's Saphnelo. There still exists a high unmet medical need for a drug that has a strong efficacy and safety profile.

ImmuPharma's LEI (Legal Entity Identifier) code : 213800VZKGHXC7VUS895.

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