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

Simbec-Orion appointed as CRO | Decision to move directly into a Phase 3 pivotal study | Compelling findings on P140's MOA

ImmuPharma PLC (LSE AIM: IMM), the specialist drug discovery and development company, is pleased to announce key updates on its late stage P140 (Lupuzor™) program, in patients with systemic lupus erythematosus ("SLE/Lupus").

Highlights

- Simbec-Orion has been appointed as the Contract Research Organisation ("CRO"), for the P140 (Lupuzor™) Phase 3 study in SLE, following extensive due-diligence and a six month tender process, involving 3 different CROs. This was conducted by ImmuPharma's clinical team and agreed with its US partner, Avion Pharmaceuticals, LLC ("Avion")

- In addition, ImmuPharma and Avion consider that a Phase 3 dose-ranging study, rather than the longer Phase 2/3 adaptive study is preferable. The direct Phase 3 route is faster to filing for approval whilst also incorporating FDA's request for demonstration of a dose-ranging in the pivotal program

- The international Phase 3 dose-ranging study design and protocol is substantially different from previous clinical trials completed by ImmuPharma. Dosing will still be a subcutaneous injection, once a month, but with significantly higher doses, which have demonstrated safety and tolerability as part of the clinical program. Two planned interim analyses during the course of the study will allow early indications of the effectiveness of P140

- Recent further insights into P140's mechanism of action ("MOA") supports its position as the only non-immunosuppressing molecule in clinical development in the industry. A new potential standard of care for SLE sufferers

- As the study continues to move forward in 2024, further details on the study's timings, protocol and key elements of the clinical trial design will be communicated at regular intervals

Appointment of Simbec-Orion as CRO

Simbec-Orion, is an experienced, full-service Contract Research Organisation, with offices across UK, Europe, and the United States, specialising in Rare & Orphan conditions. Simbec-Orion has previous direct experience in Lupus trials including conducting ImmuPharma's last Phase 3 study completed in 2018 and more recently conducted ImmuPharma's Pharmacokinetics ("PK") study completed in 2022.

P140 (Lupuzor™) ew study dosing , design and MOA

The whole P140 program was re-examined in 2021, and the Board decided that it required a completely different approach, not only to commence a new Phase 3 study in Lupus, but also to be clear on the product offering and target product profile. The three pillars of strength and confidence in our new program are dose, design and MOA.

Dose
After three FDA guidance meetings, further human and animal pharmacokinetics studies and reconciliation with efficacy demonstrated in the animal models, it was concluded that the previous dose used in clinical studies was too low. The new Phase 3 study will include dose-ranging up to 15 times higher than the original study dose of 200 micrograms.

Design
The design of the pivotal Phase 3 study includes a dose-range. This design is faster to complete than a Phase 2/3 adaptive study, while at the same time incorporating all the key objectives. We confidently expect the efficacious dose to be within this dose-range and we expect no adverse events that could lead to product label warnings seen with all other approved drugs and standard of care, which are all immunosuppressants. The study design allows two interim analyses, so there will be short term updates on clinical activity of the drug. P140 is not an immunosuppressant, so a key objective will be to taper the use of steroids which are currently standard of care. The study will also include analysis of certain biomarkers in relation to efficacy.

MOA
The lack of immunosuppression is explained by our refined MOA. All other molecules in development possess varying degrees of immunosuppression, which give rise to side effects and limit the dose that can be used to achieve efficacy.

New evidence shows that P140 restores the tolerance systems by enabling tolerogenic antigen presenting cells (like dendritic cells) to function properly. As malfunction of the tolerance systems seems to be the root cause of most if not all autoimmune diseases, it explains why P140 is so broadly efficient across most autoimmune indications in animal models. P140 is the only non-immunosuppressive molecule in the industry in clinical development for the treatment of SLE.

This distinction sets the stage for a new gold standard therapy, conveniently self-administered by the patient, once a month, which is safe and well tolerated unlike standard of care or any other molecule in development which are all immunosuppressants with significant safety warnings.

Further details on the protocol and key elements of the clinical trial design will be communicated, once the details of the trial are available on clinicaltrials.gov (a comprehensive database of privately and publicly funded clinical studies conducted around the world).

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

"It has taken longer than we anticipated to fully appraise the three CROs involved in the tender process, however, we were determined to ensure that we chose the most effective organisation that encompassed the high level clinical expertise required to ensure the highest probability of success for this trial. We are confident that Simbec-Orion meets our criteria.

Most importantly, following further detailed analysis of the protocol of this study; new insights into the MOA of P140, combined with the outstanding safety profile of the drug, we have compelling evidence that moving directly into a pivotal Phase 3 study, is the most appropriate route forward and as a result, we have a high level of confidence of the success of this study.

The second half of this year has been an extremely busy but focused period for the team and I acknowledge the frustration of shareholders for the protracted period of time to reach the decision on the appointment of the CRO. I thank everyone for their continued patience. We look forward to providing further updates on the progress of this study, together with progress on CIDP and our earlier stage programs."

Commenting further, Art Deas, CEO of Avion said:
"We continue to be excited by the potential of P140 and we look forward to working closely with ImmuPharma and Simbec-Orion, to develop this potentially life changing treatment for Lupus patients."

Fabrice Chartier, CEO of Simbec-Orion, further added:
"P140 is one of the most revolutionary and unique new drugs in development for SLE and we are delighted to have been appointed to conduct this Phase 3 study."

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.

Lupuzor™ MOA

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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 Simbec-Orion

Simbec-Orion, is an experienced, full-service Contract Research Organisation , with offices across the UK, Europe, and the United States. Established for over 45 years, and leveraging deep experience delivering first in human clinical trials, providing bespoke clinical trial services to small to mid-sized biotech and pharmaceutical partners across Europe, North America and beyond. Across the organisation scientific teams leverage both a wide therapeutic experience in clinical pharmacology, such as CNS, respiratory, dermatology, vaccines and anti-infectives, to more specialist expertise in Phase I-IV rare disease and oncology.

For more information, visit www.simbecorion.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.