12 April 2023

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

ImmuPharma receives confirmation of pre-IND meeting date with FDA for a Phase 2/3 adaptive study of P140 in CIDP

ImmuPharma PLC (LSE:IMM), the specialist drug discovery and development company, is pleased to announce further positive progress in its late-stage P140 clinical program in patients with chronic idiopathic demyelinating polyneuropathy ("CIDP").

Key highlights:

- ImmuPharma has received confirmation from the Food and Drug Administration ("FDA") for a pre- Investigational New Drug meeting date of 16 May 2023 to consider a Phase 2/3 adaptive trial study protocol for P140 in CIDP
- This will be the first pivotal stage clinical study of P140 in patients with CIDP: a rare neurological disease with high medical need
- A new Investigational New Drug ("IND") submission is required, as this will be the first time that P140 is to be studied in humans for the indication of CIDP
- An application for Orphan Drug status will be submitted following the pre-IND meeting
- The CIDP market is expected to reach global sales of US$2.7bn by 2029*

In a significant new positive step forward in its P140 platform, ImmuPharma has received confirmation from the FDA of a meeting date of 16 May 2023 for a pre-IND meeting to consider a Phase 2/3 adaptive trial study protocol for CIDP.

This will be the first pivotal stage clinical study of P140 in patients with CIDP: a rare neurological disease with high medical need. The study design was developed with our contract research organisation ("CRO") and CIDP opinion leaders from Europe and the USA.

A new IND submission is required for CIDP, as this will be the first time that P140 is to be studied in humans for the indication of CIDP. Once ImmuPharma has received the feedback from this pre-IND guidance meeting, a request will be made to FDA for a meeting date for submission of the study protocol, at a Type-B IND meeting.

An application for Orphan Drug status will be submitted following the pre-IND meeting. If approved, this will provide 7 years' market exclusivity post-marketing approval. Acceptance for Orphan Drug status is expected in H2 2023. The CIDP protocol is founded on much of the preclinical and clinical work carried out to date on P140 (Lupuzor™) in Lupus, which itself is scheduled to begin a Phase 2/3 adaptive study in Lupus patients in H2 2023.

* Source: Data Bridge Market Research, Dec 2022

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

"We are delighted to be moving P140 into its second indication for CIDP patients who suffer from a rare disease with high unmet medical need. This is a great example of P140's broad potential. Like many autoimmune and inflammatory conditions such as lupus, CIDP is caused by a similar biological mechanism. P140's unique mechanism of action selectively corrects these, making it a promising treatment option across a range of indications".

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 Chronic Idiopathic Demyelinating Polyneuropathy ("CIDP")

CIDP is a rare acquired autoimmune disorder of peripheral nerve affecting approximately 50,000 individuals across the USA/Europe. It is described by the National Institute of Neurological Disorders

and Stroke (NINDS) as a neurological disorder characterized by progressive weakness and impaired sensory function in the legs and arms. The European Academy of Neurology/ Peripheral Nerve Society (EAN/PNS) diagnosis guideline notes that CIDP is the most common immune-mediated neuropathy. CIDP can occur in both genders at any age, it is more common in young men than women. The initial generally symptoms are tingling or numbness (beginning in the toes and fingers), weakness of the arms and legs, loss of deep tendon reflexes (areflexia), fatigue, and abnormal sensations. CIDP is closely related to Guillain-Barre syndrome, and it is considered the chronic counterpart of that acute disease.

Complications of CIDP include permanent decrease or loss of sensation in areas of the body and permanent weakness or paralysis in areas of the body. These symptoms may result in impaired lower and upper limb function. For many patients the burden of treatment (side effects, cost, time, loss of autonomy) can be substantial.

In the United States, intravenous immunoglobulin (IVIG) is considered first line treatment. Multiple IVIG products including Panziga® (Pfizer), Gamunex (Grifols) and Privigen (CSL Behring) have been approved for treatment of adults with CIDP to improve neuromuscular disability and impairment. The mechanism by which IVIG improves CIDP is not clearly understood, but likely involves competing with or removing pathogenic autoantibodies, thereby preventing myelin and axonal injury. Within a setting void of inflammatory nerve attack, nerves may auto-heal and their function can be restored. In cases where nerve injury is severe or very chronic repair is an unrealistic objective, and the focus turns to preventing the disease from getting worse. Other than IVIG, corticosteroids and plasma exchange are evidence-based proven effective CIDP treatment options.

About the Pre-IND and IND

A pre-IND (pre-Investigational new drug) meeting is a drug sponsor's first formal meeting with the FDA as they begin the process of bringing a drug to market for a new disease indication. Following guidance from the FDA at the pre-IND meeting an IND is a request from a clinical study sponsor to obtain authorization from the FDA to administer an investigational drug or biological product to humans.

About the P140 Platform

Many autoimmune/inflammatory diseases involve overactive immune cells or specifically T-cells. P140's unique mechanism of action (MOA) involves modulating the activation of auto-reactive T-cells and "normalising" their overactivity rather than over-suppressing them. It is unlike other therapies which may cause too much immunosuppression in some patients. P140 is first-in its class and holds the potential as a first-line therapy in the majority of lupus patients due to its excellent safety profile to date and convenient administration. To date there are two indications for P140 due to start phase2/3 adaptive trials in H2 2023; Lupuzor™ (the trade name for P140) in lupus and P140 in CIDP.

The unique MOA of P140 has also been linked to other diseases and this has been confirmed in pre-clinical animal models. This provides scope to explore the potential of P140 in the future in asthma, irritable bowel disease, periodontitis, and gout.

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