RNS 06 March 2024



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

## Financial, Business and Portfolio Development Update

ImmuPharma PLC (LSE AIM: IMM), the specialist drug discovery and development company, is pleased to announce a positive and comprehensive financial, business and portfolio development update.

This follows on from our announcement on 19 December 2023, where we provided a detailed update on our late stage P140 (Lupuzor<sup>™</sup>) program, in patients with systemic lupus erythematosus ("SLE/Lupus").

#### **Financial Overview**

ImmuPharma would firstly like to confirm that the financing position of the Company is sufficient for its immediate requirements and it has no current plans to raise equity through the capital markets.

Future cash requirements are fully expected to be met through non-dilutive income derived from the Company's portfolio of assets including, inter alia, new commercial deals on the development portfolio, including the non-US rights for P140 (SLE/Lupus); the worldwide rights for CIDP and for BioAMB. The Company is in active discussions with a broad range of potential commercial partners with the objective of completing deals across the portfolio in 2024.

To put this all into perspective, since the reorganisation of the Company, which was initiated in August 2021, the Board of Directors has greatly simplified the Group corporate structure; reduced staff levels; eliminated unnecessary and expensive overhead costs and most importantly, focused the development portfolio into two areas; Autoimmune and Anti-Infectives.

ImmuPharma now has two late-stage autoimmune development programs through its P140 platform, for both SLE and CIDP. Also in the portfolio are two earlier anti-infective programs, BioAMB and BioCin. Prior to 2021, the portfolio was primarily focused on only P140 for SLE (Lupus). It is from this enhanced and improved development portfolio that our shareholders will see the future value accretion.

From an ongoing financial management perspective, we have seen a massive reduction of more than 75% in the annual overhead cost of the Company, compared to prior to the reorganisation. Hence, the cash needs of the Company are significantly less than historically and, as a consequence, much easier to forecast and manage.

We are expecting to announce our audited Full Year Results in May 2024.

## **Business Update**

Our business model is clear, focused and simple, for the Company to internally advance its development portfolio up to the point whereby we can enter into commercial deals with larger companies within the industry that then assume the responsibility to fund and complete the clinical development of each product through to registration and ultimately, market launch.

The financial business model underlying this approach provides an optimum number of opportunities across a range of indications and commercial deals.

In each of these potential deals we would expect to receive significant up-front payments on signing, with further receipts on achievement of development and/or sales milestones plus royalties on sales.

The therapeutic indications of our products will be entering markets which offer the realistic prospect of multi-billion dollar annual sales, which in turn, will be reflected in the levels of income we expect to be receiving in both the short, medium and long term.

It is this expectation which will drive the fundamental value of the Company and deliver the return on investment to our shareholders.

The re-focus and expansion of our portfolio development including the recent important advances in determining the clinical path through for our late stage P140 platform and elucidating its unique mechanism of action ("MOA") has generated significant interest from a wide range of potential commercial partners.

This commercial interest includes discussions on the non-US rights for P140 ("SLE"); the worldwide rights for P140 ("CIDP") and the worldwide rights for BioAMB.

Whilst there can be no guarantee of completing commercial deals, there are a broad range of discussions currently taking place and the objective is to complete deal(s) across the portfolio in 2024.

## **Development Portfolio**

## P140 | SLE/Lupus Program

Further to our update announcement on 19 December 2023 and in collaboration with Simbec-Orion, the preparatory steps for the new Phase 3 study are continuing to progress. As we reach key milestones within the study, such as: site initiations; patient recruitment and patient dosing, we will announce updates accordingly.

As a reminder, the progress update in December included:

- Simbec-Orion appointed as the Contract Research Organisation ("CRO"), for the P140 (Lupuzor™) Phase 3 study in SLE;
- Decision to go straight into an international Phase 3 dose-range study, rather than the longer and more expensive Phase 2/3 adaptive study;
- Confirmation that the current Phase 3 study is substantially different from the previous Phase 3 study completed by the Company and incorporates many changes in the protocol, including significantly higher doses; and

• Important further insights into P140's mechanism of action ("MOA") supporting its position as the only non-immunosuppressing molecule in clinical development in the industry, creating a 'first-in-class' treatment for many autoimmune diseases.

## P140 | CIDP Program

Progress has also been made in our second late-stage development program, for chronic idiopathic demyelinating polyneuropathy ("CIDP").

We are pleased to announce that Simbec-Orion, has been appointed as the CRO for this program.

In conjunction with Simbec-Orion, an IND application ("INDA") has been prepared for submission to the FDA, incorporating all their previous guidance points.

In addition, an application for Orphan Drug status for CIDP is being submitted in parallel to the INDA.

As background, in 2023, the Company received positive feedback from the FDA at a pre-Investigational New Drug meeting, that confirmed that a Phase 2/3 adaptive clinical trial will be the first pivotal stage study of P140 in patients with CIDP.

The FDA feedback recognised that P140 is suitable to be studied in another disease indication in addition to SLE and this strongly supports the underlying science and mechanism of action of P140 across several auto-immune/inflammatory diseases, again a significant breakthrough for the P140 platform.

# Anti-Infectives Program | BioAMB | for systemic fungal infections

BioAMB is a novel drug that offers a potential improvement on the limiting side effects and poor administration regime of current Amphotericin-B ("AMB") formulations. AMB is one of a last line of agents against serious and life-threatening fungal infections caused by the aspergillus family of fungi.

Although AMB is highly effective, currently marketed AMB formulations may cause serious kidney toxicity and other severe reactions. BioAMB is not a typical reformulation but a Bio-drug entity, which releases AMB as the active agent.

BioAMB, is a groundbreaking amphotericin-B variant that promises both efficiency and safety.

After multiple in vivo studies assessing the Pharmacokinetic/Pharmacodynamic ("PK/PD") and safety profile of BioAMB, the dose-effect relationship has now been assessed in Part 1 of a new dose-range pharmacodynamic study in an aspergillosis rat model. Part 1 has now been completed.

We are pleased to announce that no toxicity related to BioAMB was observed at the active dose.

We will now move forward to Part 2 of the study which will further evaluate the safety of BioAMB at the active dose and confirm the advantage of BioAMB over the other forms of AMB.

It is the intention of ImmuPharma to partner this programme and initial discussions have commenced.

### Incanthera – Financial Asset

In December 2023, ImmuPharma highlighted that Incanthera plc ("Incanthera"), the dermatology and oncology specialist, had concluded a significant commercial skincare deal with Marionnaud (part of the A.S. Watson Group) initially across Europe and with further roll outs across Asia. It confirmed that this deal is expected to generate significant revenues and profitability for Incanthera, in 2024 and beyond.

Since then, Incanthera's share price has performed strongly.

ImmuPharma owns 9.9 million shares in Incanthera, representing a 10.8% holding with a value of £916k (as at close of business on 05 March). In addition, the Company also has 7.3 million warrants in Incanthera, which are exercisable at any time.

This represents a significant financial asset for ImmuPharma.

With progressive positive news flow expected from Incanthera during 2024, it would be anticipated this will have a significant positive impact on the value of the Company's underlying shareholding.

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

*"Since our update in December 2023, ImmuPharma has continued to make positive progress within our key programs, as highlighted in this statement.* 

Against a backdrop of continued market volatility, that has adversely affected many small companies' share prices, including our own, the Board believes the underlying value of our assets continues to be strengthened.

ImmuPharma has a unique portfolio, including two late-stage assets that now have overwhelming evidence to be potential first line treatments in debilitating auto-immune diseases such as Lupus and CIDP, markets of high unmet medical need and multi-billion-dollar revenues.

It is this profile that has generated so much interest from potential commercial partners and our focus for 2024 is to secure commercial deals for these programs.

The Board is positive about the short, medium and long-term future for ImmuPharma and thanks all those shareholders who continue to support the Company."

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<sup>™</sup>), 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

## P140 MOA

The lack of immunosuppression is explained by our refined MOA. All other molecules in development demonstrate 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.

## About Lupus (Systemic Lupus Erythematosus / SLE)

Lupus is a chronic inflammatory disease which is thought to affect some 16 million individuals worldwide. The current standard of care still consists of steroid and anti-malarial therapies which many have sideeffects 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.

## About CIDP (Chronic Idiopathic Demyelinating Polyneuropathy)

CIDP is a rare acquired autoimmune disorder of peripheral nerves which is thought to affect some 90,000 individuals across US/Europe. It is a rare neurological disorder characterized by progressive weakness and impaired sensory function in the legs and arms. CIDP related disability may be substantial. In addition to the physical burdens imposed by the disease, those affected by CIDP also frequently experience economic and emotional hardship and are often burdened not only by the disease but also by the immunotherapies used to treat the disease. Other than intravenous (IVIG) and subcutaneous immunoglobulin (SCIG), corticosteroids and plasma exchange are the only other treatment options. There is still a huge unmet need for more efficacious drugs that are safer and which affect underlying disease progression.

## **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

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