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

# ImmuPharma and Avion Pharmaceuticals sign exclusive licence and development agreement and trademark agreement for Lupuzor™ with Avion to fund new international Phase III trial and commercialise in the US

ImmuPharma PLC (LSE:IMM), a specialist drug discovery and development company, announces a licence and development agreement with Avion Pharmaceuticals LLC, for the exclusive rights to Lupuzor™ in North America (United States). Lupuzor™ is ImmuPharma's lead compound, a peptide therapeutic and a first-in class autophagy immunomodulator for systemic lupus erythematosus (SLE or lupus) a potentially life-threatening auto-immune disease. In addition, Lupuzor™ also has the potential for treating other auto-immune diseases other than lupus. A trademark licence agreement also has been signed to allow Avion the use of various trademarks in connection with development, manufacture and commercialisation of products under the Licence and Development Agreement.

#### A summary of key highlights to both Agreements

- Avion and ImmuPharma will co-develop Lupuzor™ to allow registration for marketing in the US, Europe and elsewhere
- Avion will commercialise Lupuzor™ exclusively for the US.
- ImmuPharma retains all the rights to commercialise Lupuzor™, outside of the US, either through distribution partnerships or directly by ImmuPharma.
- A new optimised international Phase III trial in lupus patients (which is expected to include patients in the US, Europe and elsewhere), is targeted to commence in 2020, following agreement of the trial design between Avion, ImmuPharma and the US Food & Drug Administration ("FDA").
- Avion will fund the full expected costs of the new Phase III trial up to \$25 million.
- ImmuPharma will receive milestone payments of up to \$70 million. A \$5 million milestone payment will be paid on regulatory approval of Lupuzor™ in lupus, and \$65 million will be based on achievement of overall sales targets.
- ImmuPharma will also receive \$5 million for each additional approval, other than lupus, as Avion also has the rights, for the US, to explore further opportunities within Lupuzor™'s peptide platform for other auto-immune indications outside of lupus.
- ImmuPharma will receive from Avion tiered double-digit royalties up to 17 percent, according to pre-specified annual US sales targets.
- Avion has the right to use relevant trademarks for the development, manufacture and commercialisation of products.

## Background

ImmuPharma announced top-line trial results from its pivotal Phase III trial of Lupuzor™ in lupus patients on 17 April 2018. Further data analysis, reported on 29 May 2018 demonstrated that in the European cohort (130 patients) Lupuzor™ plus standard of care ("Active Group") showed statistically significant reductions (71.1 percent vs 48.8 percent, p=0.0218) in disease activity compared to placebo plus standard of care ("Comparator Group") in 79 patients (60.8 percent) who were anti-dsDNA autoantibody positive ("Antibody Positive").

With important insights gained from this pivotal Phase III Lupuzor™ trial, a new Phase III clinical trial design has been identified. The ability to select the most responsive patients by biomarker profile has enabled Avion and ImmuPharma to agree the most robust way forward for Lupuzor™ in lupus patients. The Licence and Development Agreement allows completion of this new optimised international Phase III trial. Avion and ImmuPharma have assessed and agreed an expected level of funding required to complete the Phase III trial, which Avion has agreed to fund in full, in return for full licensing rights over the drug within the US. ImmuPharma will receive milestone payments upon achievement of certain milestones, and tiered double-digit royalties on future revenues generated by Avion.

Outside of lupus, the Licence and Development Agreement also includes the option for Avion to explore the peptide's potential in other auto-immune diseases for the US market.

#### **Terms of the Agreements**

#### Licence and Development Agreement

The Licence and Development Agreement is between Avion and ImmuPharma (France) S.A, a subsidiary of the Company.

Avion Pharmaceuticals has licensed the exclusive rights to co-develop, with ImmuPharma, Lupuzor™ and the molecule forigerimod, to allow registration for marketing in the US, Europe and elsewhere and for Avion to commercialise Lupuzor™ for US territories. ImmuPharma retains all rights to commercialise Lupuzor™ outside of the US, either through distribution partnerships or directly by ImmuPharma. All existing clinical data and any future joint Intellectual Property will be shared between the two parties for their respective regions.

Avion has agreed to fund the full costs of the new optimised international Phase III trial for Lupuzor™ in lupus patients, based on an agreed level of expected costs up to \$25 million. It is anticipated that this new Phase III trial will commence in 2020, following agreement of the trial design between Avion, ImmuPharma and the FDA. Following recruitment of patients (to include US, Europe and elsewhere), it is envisaged that this will be a 52-week trial. Both companies will jointly steer the clinical program.

ImmuPharma will receive milestone payments of up to \$70 million. A \$5 million milestone payment will be paid on regulatory approval of Lupuzor™ in lupus, and \$65 million will be based on achievement of overall sales targets. ImmuPharma will also receive tiered double-digit royalties up to 17 percent according to pre-specified annual US sales targets.

Avion will also have the right to explore clinical development for other auto-immune indications within US territories. Additional milestone payments of \$5 million will be paid to ImmuPharma for each disease indication, outside of lupus, receiving regulatory approval.

#### Trademark Agreement

The Trademark Agreement is between Avion and ImmuPharma AG, a subsidiary of the Company.

The Trademark Agreement allows Avion to use various trademarks in connection with development, manufacture and commercialisation of products under the Licence and Development Agreement.

### Centre National de la Recherché Scientifique ("CNRS")

The CNRS is the French National Council for Scientific Research and the largest basic research organisation in Europe. The CNRS is ImmuPharma's longstanding collaboration partner and from

which Lupuzor™ was originally licensed. Through this partnership, CNRS will be entitled to receive from ImmuPharma, low double-digit royalty payments of monies received by ImmuPharma from Avion through the Licence and Development Agreement.

#### **Avion Pharmaceuticals, LLC**

Established in 2007, Avion is a US-based speciality pharmaceutical company formed to develop, acquire and market a portfolio of innovative pharmaceutical products in Women's Health and other therapeutic categories. Avion has a deep in-house expertise within medical and regulatory affairs and late-stage clinical development, together with a strong marketing and commercialisation operation. Avion's sales team reaches throughout North America with more than 100 sales representatives with significant specialist therapeutic experience. Since 2012, Avion has launched more than 55 New Drug Candidates (NDCs) and 20+ generic product extensions. Avion's launch earlier this year of a new gout product (Gloperba®) for adults is an excellent sales and marketing fit for the future commercialisation of Lupuzor™, as rheumatologists are the core prescribers and therapeutic influencers in both gout and lupus.

Commenting on the Agreements, Dimitri Dimitriou, ImmuPharma's Chief Executive Officer and Robert Zimmer, President & Chief Scientific Officer, said: "We are delighted to be entering into this partnership with Avion, a company which has a strong track record within late stage clinical development and commercialisation of products within the US, the largest market for lupus patients. Importantly, Avion's specialist sales team is well respected within the rheumatologist community, whose focus is on prescribing safe and efficacious treatments for auto-immune diseases such as lupus. This makes it a perfect fit for Lupuzor™. We look forward to a long and successful relationship with the Avion team and look forward to sharing updates on progress with shareholders over the next period."

Art Deas, Chief Executive Officer, Avion Pharmaceuticals added: "Avion is extremely pleased to sign this partnership with ImmuPharma. After in-depth due-diligence around Lupuzor, its mechanism of action and learnings within the initial Phase III results, we believe that Lupuzor, has a unique position within lupus that sets it apart from competition, and we are delighted to be extending our footprint within this therapeutic area. With approximately 1.5 million patients in the US suffering from lupus, there is a significant unmet need for a safe and effective drug for this debilitating disease that we believe Lupuzor, can meet. We look forward to forging a strong and successful relationship with ImmuPharma going forward."

This announcement contains inside information for the purposes of Article 7 of Regulation (EU) 596/2014. ("MAR")

For further information please contact:

ImmuPharma PLC (www.immupharma.com) Tim McCarthy, Chairman Dimitri Dimitriou, Chief Executive Officer Lisa Baderoon, Head of Investor Relations	+ 44 (0) 207 152 4080 + 44 (0) 7721 413496
SPARK Advisory Partners Limited (NOMAD) Neil Baldwin Vassil Kirtchev	+44 (0) 203 368 8974
Stanford Capital Partners (Joint Broker) Patrick Claridge, John Howes	+44 (0) 203 815 8880
SI Capital (Joint Broker) Nick Emerson	+44 (0) 1483 413500

#### **Notes to Editors**

#### **About ImmuPharma PLC**

ImmuPharma PLC (AIM: IMM) is a specialty biopharmaceutical company that discovers and develops peptide-based therapeutics. The company portfolio includes novel peptide therapeutics for autoimmune diseases, metabolic diseases and cancer. The lead program, Lupuzor™, is a first-in class autophagy immunomodulator which is in Phase III 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 <a href="https://www.immupharma.com">www.immupharma.com</a>.

#### **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 <a href="https://www.avionrx.com">www.avionrx.com</a>.