

### PRESS RELEASE - IMMUNOCORE LIMITED

# Immunocore's IMCgp100 Granted Orphan Drug Designation by US FDA for the Treatment of Uveal Melanoma

(Oxford, UK, 25 January 2016) Immunocore, a world-leading biotechnology company developing novel T cell receptor (TCR) based biological drugs to treat cancer, infectious diseases and autoimmune disease, today announced that the US Food and Drug Administration (FDA) has granted Orphan Drug Designation to its lead programme, IMCgp100, for the treatment of uveal melanoma. The Orphan Drug status qualifies Immunocore for a number of development incentives and will enable Immunocore to receive fast track registration for IMCgp100, its lead ImmTAC (Immune mobilising mTCR Against Cancer) therapeutic.

Uveal melanoma, a rare disease in which cancer cells form in the tissues of the eye, comprises approximately 3% of all melanomas, and is the primary intraocular malignancy of the adult eye. There are currently no effective treatments on the market for this debilitating disease.

For a drug to qualify for orphan drug designation both the drug and the disease must meet certain criteria specified in the Orphan Drug Act (ODA) and FDA's implementing regulations at 21 CFR Part 316.

IMCgp100 is Immunocore's wholly-owned and most advanced ImmTAC, currently in Phase IIa clinical trials for the treatment of late stage cutaneous and uveal melanoma. To date, more than 85 patients have been treated with IMCgp100.

IMCgp100 was also accepted last year to participate in the European Medicines Agency's (EMA) Adaptive Pathways Pilot Programme, part of the EMA's strategy of providing timely access for patients to new medicines to treat serious conditions with high unmet medical need.

Eliot Forster, Chief Executive Officer of Immunocore, commented: "Immunocore now has the opportunity to fast-track this important programme, which we believe has the scope to offer a treatment option to people who currently have none. We look forward to accelerating the ongoing clinical programme with IMCgp100."

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# **Notes for editors**

#### **About Immunocore**

Immunocore is one of the world's leading biotechnology companies, with a highly innovative immuno-oncology platform technology called ImmTACs. ImmTACs are a novel class of biologic drugs based on the Company's proprietary T cell receptor (TCR) technology which have the potential to treat diseases with high unmet medical need including cancer, infectious diseases and autoimmune diseases. Immunocore, based on decades of world-leading scientific innovation in the discovery of HLA targets and T cell receptor technology, has a pipeline of wholly-owned and partnered ImmTAC programmes with robust clinical data, validated by collaborations with world-leading pharmaceutical companies. Immunocore aims to leverage the utility of its platform across a wide range of indications to become a Premier Biotech company and world-leader in its field.

Immunocore's world-leading science and strong IP position has attracted major pharmaceutical companies including Genentech, GlaxoSmithKline, MedImmune, the biologics division of AstraZeneca, via discovery collaborations, as well as a co-discovery and co-development partnership with Lilly. The Company has also entered into combination trials with its lead programme, IMCgp100 in melanoma, with Medimmune and Lilly. Founded in 2008 originally out of Oxford University and headquartered outside Oxford, Immunocore now has more than 185 staff. Immunocore's current investors are well-renowned, leading international institutions including Woodford Investment Management, Malin Corporation, Eli Lilly and Company, RTW Investments, Fidelity Management & Research Company as well as other private shareholders. For more information, please visit <a href="https://www.immunocore.com">www.immunocore.com</a>

# **About ImmTACs**

Immunocore's proprietary technology is focused on small protein molecules called ImmTACs (Immune mobilising mTCR Against Cancer) that enable the immune system to recognise and kill cancerous or bacterially/virally infected cells. Immunocore's ImmTACs, a new class of drug with ultra-high affinity for intracellular cancer targets, are synthetic, soluble T cell receptors (TCRs) that recognise diseased cells containing disease specific targets. The ImmTACs enable circulating T-cells to selectively identify and kill diseased cells. The ImmTAC platform is unique in its high specificity and potency and broad applicability to a wide range of intracellular targets and disease indications. ImmTACs can access up to nine-fold more targets than typical antibody-based therapies, including monoclonal antibodies.



TCRs naturally recognise diseased cells and Immunocore's world-leading competitive advantage is its ability to engineer high affinity TCRs and link them to an antibody fragment that activates a highly potent and specific T cell response to recognise and destroy cancer cells. The most advanced ImmTAC, IMCgp100, is currently in Phase IIa clinical trials for the treatment of late stage melanoma. Immunocore has a growing internal pipeline of ImmTACs addressing many different cancer types and has developed a broad database of intracellular cancer targets.

ImmTACs can address a significantly larger range of disease indications than currently respond to existing immuno-oncology agents and combine the characteristics of very high potency, encouraging safety and low cost of goods.

### **About Uveal Melanoma**

Melanoma arises from pigment containing cells (melanocytes) present in the skin, eye and mucous membranes. Melanoma most frequently occurs in the skin, however ocular melanoma arises from pigmented cells in the eye. The primary cause of melanoma is thought to be radiation induced DNA damage from ultraviolet (UV) light exposure. Melanoma is the most deadly of skin cancers. Globally, in 2012, melanoma occurred in 232,000 people and resulted in 55,000 deaths. Uveal melanoma (UM) is a rare type of melanoma where the incidence has ranged from 5.3 to 10.9 cases per million (Singh 2003). Despite its rare incidence rate (representing approximately 3% of melanoma cases, approximately 4000 cases globally per year), UM is the most frequent primary intraocular malignancy of the adult eye in 85% of cases (Patel 2011, Maio 2013). \*