



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

January 25, 2016

(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."*

Please click on the link below to download the full Press Release: