

PRESS RELEASE - IMMUNOCORE LIMITED

# Immunocore Announces Positive Clinical Trial Data for Novel First-in-Class Immunotherapy at AACR Annual Meeting 2015

# IMCgp100 shows partial and complete durable responses in Phase I/IIa trial in patients with advanced melanoma

**(Oxford, UK, 20 April 2015)** Immunocore Limited, a world-leading biotechnology company developing novel biological drugs to treat cancer, viral infections and autoimmune diseases, today announced clinical trial data from the Phase I/IIa study of its lead programme IMCgp100, at the American Association for Cancer Research (AACR) Annual Meeting 2015, in Philadelphia, USA.

The clinical data, presented by Mark Middleton MD, Professor of Experimental Cancer Medicine at the University of Oxford, and Principal Investigator for the study, demonstrated an excellent safety profile with objective clinical responses achieved in cutaneous and ocular melanoma in addition to ipilimumab and pembrolizumab refractory patients. 58 patients in total have received treatment to date on the trial.

In a cohort of 14 patients who were of either positive or unknown gp100 status, treated with the weekly regimen in the Phase IIa portion of the trial, there were four objective clinical responses, including one complete response, lasting 4.7 months, and three partial responses, lasting 5.9 - 18+ months, including in a patient refractory to ipilimumab.

Responses were durable, with two partial responders continuing 18+ months. Importantly, two of the objective responses, one complete and one partial, were observed in the only two patients enrolled in the expansion cohort with ocular melanoma. This encouraging clinical activity suggests that ocular melanoma is an important subgroup of melanoma for IMCgp100 based on the high unmet need in this indication.

The Phase I portion of the open label trial was designed to determine the maximum tolerated dose of IMCgp100 in HLA-A2 positive patients with Stage 4 or unresectable Stage 3 melanoma for use in either a weekly dosing regimen, or a high intensity regimen consisting of four consecutive daily doses in three week cycles. Maximum tolerated dose for weekly administration was determined as 600ng/Kg, which was transitioned to a total dose of 50 mcg. Dose escalation of the high intensity regimen is continuing.

"Last year at the AACR Annual Meeting, we reported the results of the Phase I dose escalation portion of the clinical trial, which showed that IMCgp100 was well tolerated and had efficacy in some patients with advanced melanoma," Mark Middleton commented. "This year, we are reporting data from 17 patients treated with the



maximum tolerated dose of 600 nanograms of IMCgp100 per kilogram or an absolute dose of 50 micrograms of IMCgp100 as part of the Phase I and Phase IIa portions of the trial.

"Among these patients, we observed lasting tumour responses for both cutaneous and ocular melanoma," Middleton added. "Importantly, responses were even observed in patients with advanced melanoma that was resistant to the immune checkpoint inhibitors that have recently become standard of care in many locations."

"These results support the promise of IMCgp100 as a treatment for cutaneous melanoma as well as ocular melanoma. We are particularly pleased with the durability of the response which has been the challenge with current treatments. Our new class of bispecific biologics, ImmTACs have the potential to treat a broad range of solid tumours either as monotherapies or in combination with other immunotherapies to create potentially best in class treatment regimes," said Eliot Forster, Chief Executive Officer of Immunocore.

### For more information, please contact:

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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, viral infections and autoimmune diseases. Immunocore has a pipeline of wholly-owned and partnered ImmTAC programmes with robust clinical data, based on decades of world-leading scientific innovation in the discovery of HLA targets and T cell receptor technology and 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. Founded in 2008 originally out of Oxford University and headquartered outside Oxford, Immunocore now has more than 140 staff. Immunocore is well funded and owned by a group of long-term private investors. For more information, please visit www.immunocore.com

#### **About Melanoma**

Melanoma is a form of skin cancer that accounts for less than five per cent of cases but causes the vast majority of skin cancer deaths. Incidence rates are increasing more rapidly than for any other cancer and by 2019 there are forecast to be around 227,000 cases diagnosed worldwide each year (Datamonitor report DMHC2628). Unlike other common cancers, melanoma has a wide age distribution.

Patients who are diagnosed early are treatable with surgical resection, but for many the disease will recur. Once melanoma progresses to late stage disease and becomes metastatic the prognosis is poor, with a median survival period of around eight months for patients with advanced melanoma. A number of agents have been approved for melanoma recently and these have shown significant responses in patients, though long term response durability in the majority of patients remains elusive.

## **About IMCgp100 and 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 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 and has very high specificity and potency as well as broad applicability to a wide range of intracellular targets. 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. Following completion of a Phase I study at the end of 2013, which showed promising results with an encouraging safety profile and early signs of efficacy, Immunocore initiated a Phase IIa study to optimize the dosing regimen of IMCgp100. To date IMCgp100 has been investigated in 58 patients.



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 be manufactured in a high-yield, fully-scalable and low cost microbial system. They are extremely stable with a multi-year shelf-life.