IMMUNOCORE

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

May 20, 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.**

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