

## PRESS RELEASE

### **New IMCgp100-102 Data Show Durable Response and Robust Overall Survival Rate in Patients with Metastatic Uveal Melanoma**

- *Currently no effective treatment for a rare cancer that affects approximately 4,000 globally<sup>1</sup>*
- *Update from IMCgp100-102 trial to be presented at 2018 ASCO annual meeting*
- *Pivotal trials with IMCgp100 in metastatic uveal melanoma continue to enroll*

(Oxford, UK and Conshohocken, US, 4 June 2018) Patients with metastatic uveal melanoma (mUM) treated with IMCgp100 continued to experience a durable tumour response with a median follow up of 19.1 months, without yet reaching median overall survival (OS), according to new Phase I research to be presented today at the American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago.<sup>2</sup> IMCgp100 is the wholly-owned, lead programme from Immunocore Limited, a leading T-cell receptor (TCR) company focused on delivering first-in-class biological therapies that transform lives.

Although rare, uveal melanoma is the most common form of adult eye cancer.<sup>3</sup> When it metastasises beyond the eye, less than half of patients will survive for one year.<sup>4</sup> Of the 19 HLA-A\*0201+ patients enrolled in Phase I of the Phase I/II dose escalation trial, 17 were evaluated for efficacy. Among these patients, treatment with IMCgp100 was associated with an objective response rate of 18% (90% confidence interval [4,30]) and a one-year overall survival rate of 74% (95% confidence interval [48,88]) at the time of data cut-off.<sup>2</sup>

*“Survival rates in uveal melanoma have remained largely unchanged for decades, and it is difficult to treat once it advances to metastatic disease,”* said Dr. Takami Sato, Department of Medical Oncology, Kimmel Cancer Center, Thomas Jefferson University and lead investigator. *“These data provide compelling evidence that IMCgp100 may offer hope to this underserved patient population.”*

Additional exploratory survival analyses also indicated prolonged OS was associated with a number of pharmacodynamic outcomes, including lymphocyte trafficking, providing encouraging evidence supporting the proposed mechanism of action of IMCgp100.<sup>2</sup>

*“Immunocore is focused on transforming the lives of patients with some of the most challenging diseases, such as metastatic uveal melanoma, for which there is currently no standard of care,”* said Andrew Hotchkiss, Chief Executive Officer at Immunocore. *“Although these are early findings, we are encouraged by the emerging clinical data and focused on advancing our pivotal trials.”*

The most common adverse events in the Phase I arm included pruritus (severe itching of the skin; 90%), pyrexia (fever) and fatigue (84%), and hypotension (74%).<sup>2</sup> Dose limiting toxicities were observed in 3 patients; all were reversible abnormalities in liver function tests (Grade 3 or 4 ALT/AST changes). There were no IMCgp100-related AEs that resulted in discontinuation or death.<sup>2</sup>

## About Metastatic Uveal Melanoma

Uveal melanoma is an aggressive form of melanoma which affects the eye, with a poor prognosis and no standard of care.<sup>5</sup> Although it is the most common primary intraocular malignancy in adults,<sup>3</sup> the diagnosis is rare, with approximately 4,000 new patients diagnosed globally each year (1,500 cases/year in US).<sup>1</sup> Up to 50% of people with uveal melanoma will eventually develop metastatic disease.<sup>5,6</sup> When the cancer spreads beyond the eye, only approximately 40% of patients will survive for one year.<sup>4</sup>

## About the IMCgp100-102 Phase I/II Trial

In this study, IMCgp100 is administered on a weekly basis with an intra-patient escalation dosing regimen. The dose escalation portion of the study has been completed, which identified the recommended Phase II intra-patient dose. The Phase II portion of the study is ongoing evaluating both the safety and efficacy in patients with metastatic uveal melanoma. The currently enrolling cohort is assessing IMCgp100 in patients who have experienced disease progression after 1 or 2 prior lines of therapy, which may include up to 1 line of liver directed therapy. Approximately 150 patients will be enrolled in the Phase II portion and the estimated enrolment completion date is September 2019.

## About the IMCgp100 Programme

IMCgp100 is a novel bi-specific biologic T cell redirection therapy that specifically targets the melanoma-associated antigen gp100, and which is now in pivotal studies for mUM. IMCgp100 was granted Orphan Drug Designation by the US Food and Drug Administration in 2016 and Promising Innovative Medicine designation under UK Early Access to Medicines Scheme in 2017. For more information about enrolling IMCgp100 clinical trials for metastatic uveal melanoma, please visit [ClinicalTrials.gov](https://ClinicalTrials.gov/ct2/show/study/NCT02570308) ([NCT02570308](https://ClinicalTrials.gov/ct2/show/study/NCT02570308), [NCT03070392](https://ClinicalTrials.gov/ct2/show/study/NCT03070392)).

## About ImmTAC® Molecules

Immunocore's proprietary TCR (T Cell Receptor) technology generates a novel class of bi-specific biologics called ImmTAC (Immune mobilising monoclonal TCRs Against Cancer) molecules that enable the immune system to recognise and kill cancerous cells. ImmTAC molecules are based on synthetic, soluble TCRs engineered to recognise intracellular cancer antigens with ultra-high affinity and selectively kill cancer cells via an anti-CD3 immune-redirecting effector function. ImmTAC molecules can access up to nine-fold more target antigens than typical antibody-based approaches, including monoclonal antibodies. Based on the demonstrated mechanism of T cell infiltration into human tumours, the ImmTAC mechanism of action holds the potential to tackle solid "cold" low mutation rate tumours, the majority of tumours that do not adequately respond to currently available immunotherapies.

## About Immunocore

Immunocore, a leading T Cell Receptor (TCR) biotechnology company, is focused on delivering first-in-class biological therapies that have the potential to transform the lives of people with serious diseases. The Company's primary therapeutic focus is oncology and it also has programs in infectious and autoimmune diseases. Immunocore has a pipeline of proprietary and partnered programs in development and the lead programme, IMCgp100, has entered pivotal clinical studies as a treatment for patients with metastatic uveal melanoma. Partners include Genentech, GlaxoSmithKline, AstraZeneca,

Lilly, and the Bill and Melinda Gates Foundation. Immunocore is headquartered at Milton Park, Oxfordshire, UK, with an office outside Philadelphia, USA. The Company is privately held by a broad international investor base. For more information, please visit [www.immunocore.com](http://www.immunocore.com).

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<sup>1</sup> Data on file

<sup>2</sup> Sato, T. *et al.* Redirected T cell lysis in patients with metastatic uveal melanoma with gp100-directed TCR IMCgp100: Overall survival findings. Presented at ASCO 2018 (abstract 9521).

<sup>3</sup> Mahendraraj K, Lau CS, Lee I, *et al.*, 2016. Trends in incidence, survival, and management of uveal melanoma: a population-based study of 7,516 patients from the surveillance, epidemiology, and end results database (1973–2012). *Clinical Ophthalmology*, 10, 2113.

<sup>4</sup> Khoja L, Atenafu E, Joshua A, and The International Rare Cancer's Initiative-Ocular Melanoma Group. 2016. Meta-analysis of phase II trials in metastatic uveal melanoma (MUM) to determine progression-free (PFS) and overall survival (OS) benchmarks for future phase II trials: An irci-ocular melanoma initiative. *Journal of Clinical Oncology* 34:15\_suppl, 9567-9567.

<sup>5</sup> Carvajal, RD, Schwartz, GK, Tezel, T, *et al.*, 2017. Metastatic disease from uveal melanoma: treatment options and future prospects. *British Journal of Ophthalmology*, 101(1), 38-44.

<sup>6</sup> Kujala E, Mäkitie T, Kivelä T. 2003. Very long-term prognosis of patients with malignant uveal melanoma. *Investigative Ophthalmology & Visual Science*, 44, 4651.