PRESS RELEASE

Immunocore’s IMCgp100 Receives Promising Innovative Medicine (PIM) Designation Under UK Early Access to Medicines Scheme (EAMS) for the Treatment of Patients with Uveal Melanoma

(Oxford, UK and Conshohocken, US, 11 December 2017) Immunocore Limited, the world’s leading TCR company focused on delivering first-in-class biological therapies that transform lives, today announces that it has been informed by the UK’s Medicines and Healthcare Products Regulatory Agency (MHRA) that IMCgp100 has been granted Promising Innovative Medicines (PIM) designation for the treatment of patients with metastatic uveal melanoma.

PIM designation is an early indication that IMCgp100 is a promising candidate for the UK’s Early Access to Medicines Scheme (EAMS), intended for the treatment, diagnosis or prevention of metastatic uveal melanoma. This is based on early Phase I clinical trial data published at the Society for Immunotherapy of Cancer (SITC) annual meeting in November. IMCgp100 will be a suitable candidate for entry into Step II of the EAMS process, for which Immunocore is in a pivotal registrational clinical trial in patients with metastatic uveal melanoma. Following this, IMCgp100 will enter the EAMS scientific opinion assessment step.

For more information on clinical trials involving IMCgp100, please visit clintrials.gov.

James Sandy, Chief Development Officer at Immunocore, commented: “We are delighted by the MHRA’s decision to award PIM designation to IMCgp100, which gives us scope to accelerate the approval process for IMCgp100, and bringing us a step closer toward making IMCgp100 available for patients with uveal melanoma, for which there are currently no effective treatment options available.”

IMCgp100 was granted Orphan Drug Designation by the US Food and Drug Administration (FDA) in January 2016 and participated in the EMA’s Adaptive Pathways Pilot Programme.

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Notes for editors

About Immunocore

Immunocore, the world’s leading TCR (T cell receptor) company, is focused on delivering first-in-class biological therapies that transform lives. The Company’s therapeutics have broad applicability across a wide range of indications, including solid tumours and infectious diseases. Immunocore has a pipeline of proprietary and partner products in development and the lead programme, IMCgp100, is in pivotal clinical studies as a monotherapy for the treatment of patients with metastatic uveal melanoma. Partners include Genentech, GlaxoSmithKline, AstraZeneca and Lilly. Immunocore is headquartered near Oxford, UK, with offices near Philadelphia, USA. The Company is privately held by a broad international and private investor base. For more information, please visit www.immunocore.com.

About the UK Early Access to Medicines Scheme (EAMS)

The UK’s industry-sponsored EAMS aims to give patients with life threatening or seriously debilitating conditions access to medicines that do not yet have a marketing authorization when there is a clear unmet medical need. The EAMS is a two-step process: Step I is the Designation as a Promising Innovation Medicine (PIM). The PIM designation is an early indication that a medicinal product is a promising candidate for EAMS and gives reassurance that its clinical development is on track by having an early review of its data by the medicines regulator. Step II is the Scientific Opinion by the Medicines and Healthcare products Regulatory Agency (MHRA, UK regulatory agency). The Scientific Opinion describes the benefits and risks of the medicine and supports the prescriber and patient to make a decision on using the medicine before its license is approved.

About IMCgp100

IMCgp100 is a novel bispecific biologic, an ImmTAC®, which is capable of redirecting T cells against the melanocyte-associated antigen gp100, and which is now in pivotal studies for metastatic uveal melanoma. In the first-in-human (FIH) clinical trial (IMCgp100-01), preliminary efficacy of IMCgp100 in advanced uveal and cutaneous melanoma was observed. Immunocore has demonstrated durable tumour responses and strong one-year overall survival data showing a near doubling in the average rate of overall survival compared with studies of other agents, from two Phase I clinical trials of IMCgp100, in metastatic uveal melanoma. IMCgp100 was granted orphan drug designation by the US Food and Drug Administration in 2016. In addition to the uveal melanoma studies, IMCgp100 is currently in a clinical combination study with MedImmune’s checkpoint inhibitors Imfinzi™ (durvalumab, anti-PDL-1) and tremelimumab (anti-CTLA-4) in patients with metastatic cutaneous melanoma who no longer respond to anti-PD-1 therapies.

About ImmTAC® Molecules

Immunocore’s proprietary TCR (T cell receptor) technology generates small protein drugs called ImmTAC (Immune mobilising monoclonal TCRs Against Cancer) molecules that enable the immune system to recognise and kill cancerous cells. ImmTAC molecules are a new class of drugs with ultra-high affinity for intracellular cancer targets, based on synthetic, soluble TCRs that naturally recognise cells containing disease specific targets and selectively kill them. ImmTAC molecules can access up to nine-fold more targets than typical antibody-based therapies, including monoclonal antibodies. They also have the unique ability to tackle solid “cold” low mutation rate tumours, the majority of tumours, that do not adequately respond to currently available immunotherapies. ImmTACs have an encouraging safety profile and are highly scalable, with a low cost of goods. Immunocore’s TCR-based approach has a broad applicability to a wide range of targets and disease indications including infectious diseases alongside solid and liquid tumours.
About Uveal Melanoma

Uveal melanoma is a rare and aggressive form of melanoma which affects the eye with a poor prognosis and no standard of care. Although uveal melanoma is the most common primary intraocular malignancy in adults, representing approximately 3-4% of all melanomas, the diagnosis is rare with approximately 4,000 new patients globally diagnosed per year (1,500 cases/year in US) all stages combined (Chattopadhyay, 2016). Up to 50% of patients with local disease will develop metastases (Carvajal, 2017; Kujala, 2003). Despite extensive investigation of metastatic uveal melanoma in the clinic, to date no systemic treatment has demonstrated improved survival and no effective therapy has been identified in this disease setting (Carvajal, 2017).