



## Immunocore Announces UK's Medicines and Healthcare Products Regulatory Agency (MHRA) Accepts Marketing Authorization Application for Tebentafusp in Metastatic Uveal Melanoma

September 8, 2021

### PRESS RELEASE

#### Immunocore Announces UK's Medicines and Healthcare Products Regulatory Agency (MHRA) Accepts Marketing Authorization Application for Tebentafusp in Metastatic Uveal Melanoma

**MHRA's acceptance follows acceptances by the U.S. Food and Drug Administration and European Medicines Agency of Biologics License Application and Marketing Authorisation Application respectively for Tebentafusp in Metastatic Uveal Melanoma**

#### **Tebentafusp application part of the FDA's Project Orbis initiative in the UK**

(OXFORDSHIRE, England & CONSHOHOCKEN, Penn. & ROCKVILLE, Md., US, 8 September 2021) [Immunocore](#) (Nasdaq: IMCR), a late-stage biotechnology company pioneering the development of a novel class of T cell receptor (TCR) bispecific immunotherapies designed to treat a broad range of diseases, including cancer, infectious and autoimmune disease, today announces that United Kingdom's Medicines and Healthcare products Regulatory Agency (MHRA) has accepted a Market Authorisation Application (MAA) seeking the approval of tebentafusp (IMCgp100) for the treatment of patients with metastatic uveal melanoma (mUM).

Tebentafusp is also being reviewed in the UK under the U.S. Food and Drug Administration's (FDA) Project Orbis initiative, which enables concurrent review by the health authorities in participating partner countries. As previously announced, the FDA and European Medicines Agency have accepted the Biologics License Application (BLA) and MAA respectively for tebentafusp. In the United States, the BLA was initiated and will be reviewed under the Real-Time Oncology Review (RTOR) pilot program.

The regulatory submissions for tebentafusp are based on data from the randomized Phase 3 IMCgp100-202 clinical trial evaluating tebentafusp in previously untreated metastatic uveal melanoma, a cancer that has historically proven to be frequently insensitive to other immunotherapies. In the final study analysis, tebentafusp demonstrated clinically and statistically significant superior overall survival (OS) benefit as a monotherapy. The primary endpoint was achieved with the OS Hazard Ratio (HR) in the intent-to-treat population favoring tebentafusp, HR=0.51 [95% CI (0.37, 0.71); p<0.0001] over investigator's choice (82% pembrolizumab; 12% ipilimumab; 6% dacarbazine).

**Bahija Jallal, Chief Executive Officer of Immunocore, said:** *"We are delighted that the MHRA has accepted our application for tebentafusp and the FDA has selected tebentafusp for the Project Orbis initiative. As a UK-founded biotech company pioneering the field of TCR therapeutics, we are encouraged with these regulatory milestones that brings us closer to helping people with metastatic uveal melanoma in the UK and abroad. The regulatory agencies recognise the urgent need for an approved treatment specific to mUM, an aggressive form of cancer for which the recommended option for patients is enrolment into a clinical trial."*

### About Immunocore

Immunocore is a late-stage biotechnology company pioneering the development of a novel class of TCR bispecific immunotherapies called ImmTAX – Immune mobilizing monoclonal TCRs Against X disease – designed to treat a broad range of diseases, including cancer, infectious and autoimmune. Leveraging its proprietary, flexible, off-the-shelf ImmTAX platform, Immunocore is developing a deep pipeline in multiple therapeutic areas, including five clinical stage programs in oncology and infectious disease, advanced pre-clinical programs in autoimmune disease and multiple earlier pre-clinical programs. Immunocore's most advanced oncology therapeutic candidate, tebentafusp, has demonstrated an overall survival benefit in a randomized Phase 3 clinical trial in metastatic uveal melanoma, a cancer that has historically proven to be insensitive to other immunotherapies.

### About Tebentafusp

Tebentafusp is a novel bispecific protein comprised of a soluble T cell receptor fused to an anti-CD3 immune-effector function. Tebentafusp specifically targets gp100, a lineage antigen expressed in melanocytes and melanoma, and is the first molecule developed using Immunocore's ImmTAC technology platform designed to redirect and activate T cells to recognise and kill tumour cells. Tebentafusp has been granted Priority Review; Real Time Oncology Review; Breakthrough Therapy designation; Fast Track designation; and orphan drug designation by the FDA in the United States; orphan drug status in the European Union; and Promising Innovative Medicine (PIM) designation under the UK Early Access to Medicines Scheme for metastatic uveal melanoma. Tebentafusp has also been granted accelerated assessment by the EMA's Committee for Medicinal Products for Human Use (CHMP). Tebentafusp is being reviewed under the FDA's Project Orbis initiative, which enables concurrent review by the health authorities in partner countries that have requested participation. For more information about enrolling in tebentafusp clinical trials for metastatic uveal melanoma, please visit [ClinicalTrials.gov](#) (NCT03070392).

### About ImmTAC<sup>®</sup> Molecules

Immunocore's proprietary T cell receptor (TCR) technology generates a novel class of bispecific biologics called ImmTAC (Immune mobilising monoclonal TCRs Against Cancer) molecules that are designed to redirect the immune system to recognise and kill cancerous cells. ImmTAC molecules are soluble TCRs engineered to recognise intracellular cancer antigens with ultra-high affinity and selectively kill these cancer cells via an anti-CD3 immune-activating effector function. Based on the demonstrated mechanism of T cell infiltration into human tumours, the ImmTAC mechanism of action holds the potential to treat hematologic and solid tumours, regardless of mutational burden or immune infiltration, including immune "cold" low mutation rate tumours.

### About Uveal Melanoma

Uveal melanoma is a rare and aggressive form of melanoma, which affects the eye. Metastatic uveal melanoma typically has a poor prognosis and

has no currently accepted optimal management or treatment. Although it is the most common primary intraocular malignancy in adults, the diagnosis is rare, with approximately 8,000 new patients diagnosed globally each year (1,600-2,000 cases per year in the United States). Up to 50% of people with uveal melanoma will eventually develop metastatic disease. When the cancer spreads beyond the eye, only approximately half of patients will survive for one year.

### **Forward Looking Statements**

This press release contains “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995, including, but not limited to, statements regarding the efficacy, safety and therapeutic potential of tebentafusp; the clinical development of tebentafusp; the potential benefit of Breakthrough Therapy Designation, Fast Track Designation, Orphan Drug Designation, Priority Review or Accelerated Assessment for tebentafusp; the likelihood of obtaining regulatory approval of tebentafusp; the regulatory approval path and potential commercialization plans for tebentafusp including the timing of such approval decisions, including (i) the PDUFA target action date of February 23, 2022 and (ii) receipt of a CHMP opinion; the expected benefits of tebentafusp including that tebentafusp would be a therapeutic option treatment for metastatic uveal melanoma; and potential growth opportunities and trends in oncology. Any forward-looking statements are based on management’s current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements, many of which are beyond the Company’s control. These risks and uncertainties include, but are not limited to, the impacts of the COVID-19 pandemic on the Company’s business, clinical trials and financial position; unexpected safety or efficacy data observed during preclinical studies or clinical trials; clinical trial site activation or enrolment rates that are lower than expected; changes in expected or existing competition; changes in the regulatory environment; and the uncertainties and timing of the regulatory approval process. For a discussion of other risks and uncertainties, and other important factors, any of which could cause our actual results to differ from those contained in the forward-looking statements, see the section titled “Risk Factors” in the Company’s Annual Report on Form 20-F filed with the Securities and Exchange Commission on March 25, 2021, as well as discussions of potential risks, uncertainties, and other important factors in the Company’s subsequent filings with the Securities and Exchange Commission. All information in this press release is as of the date of the release, and the Company undertakes no duty to update this information except as required by law.

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