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Immunocore announces publication of phase 3 data comparing tebentafusp with investigator's choice in The New England Journal of Medicine

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Press Release

Immunocore announces publication of phase 3 data comparing tebentafusp with investigator's choice in *The New England Journal of Medicine*

Tebentafusp demonstrated prolonged overall survival (OS) compared to investigator's choice therapy in previously untreated, metastatic uveal melanoma patients

Tebentafusp is first T cell receptor (TCR) therapeutic to demonstrate a survival benefit

(OXFORDSHIRE, England & CONSHOHOCKEN, Penn. & ROCKVILLE, Md., US, 22 September 2021) Immunocore Holdings Plc (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, infection and autoimmune disease, today announces that data from a phase 3 randomized trial comparing tebentafusp (IMCgp100) with investigator's choice in first-line metastatic uveal melanoma (mUM) has been published in The New England Journal of Medicine (NEJM).

The paper concluded that tebentafusp is the first systemic treatment to show a survival benefit in mUM and should become a new treatment option for this poor prognosis disease.

"The publication of these phase 3 data in a leading peer-reviewed scientific publication like NEJM demonstrates the significance of Immunocore's work in the field of TCR therapy," said Bahija Jallal, Chief Executive Officer of Immunocore. "This further validates the potential of tebentafusp to provide a much needed treatment option for patients with metastatic uveal melanoma, making a meaningful difference to patients' lives. In addition, we believe these data show the broader potential of Immunocore's TCR technology for the treatment of other solid tumors."

Results from the randomized, open-label, phase 3 trial of tebentafusp vs. investigator's choice in previously untreated HLA-A*02:01-positive patients with mUM demonstrated a statistically significant and clinically meaningful improvement in overall survival (OS) as a first-line treatment in mUM. The OS Hazard Ratio (HR) in the intent-to-treat population favored tebentafusp, HR=0.51 (95% CI: 0.37, 0.71); p< 0.0001, over investigator's choice (82% pembrolizumab; 12% ipilimumab; 6% dacarbazine). Treatment-related adverse events were manageable and consistent with the proposed mechanism.

Tebentafusp has been granted Breakthrough Therapy Designation, Fast Track designation and orphan drug designation by the U.S. Food and Drug Administration (FDA) and Promising Innovative Medicine (PIM) designation under the UK Early Access to Medicines Scheme for metastatic uveal melanoma. Immunocore's biologics license application for approval of tebentafusp for the treatment of HLA-A*02:01-positive adult patients with metastatic uveal melanoma was recently accepted by the FDA. In addition, the European Medicine Agency (EMA)'s Committee for Medicinal Products for Human Use (CHMP) accepted Immunocore's Marketing Authorisation Application (MAA).

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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 tumor 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® Molecules

Immmunocore'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 design, progress, timing, scope and results of the Company’s clinical trials including IMCgp100-202, the anticipated timing of disclosure of results of clinical trials, plans for initiating future clinical trials and extension studies, the progress of the Company’s development programs including tebentafusp, the potential benefit of Breakthrough Therapy Designation, Fast Track designation, orphan drug designation or Promising Innovative Medicine designation for tebentafusp, the likelihood of obtaining regulatory approval of any of the Company’s product candidates including tebentafusp, and the regulatory approval path for tebentafusp. 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 enrollment 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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