



## Immunocore presents new data on KIMMTRAK (tebentafusp-tebn) in metastatic cutaneous (mCM) and uveal melanoma (mUM) at the 2022 American Society of Clinical Oncology (ASCO) Annual Meeting

June 6, 2022

### PRESS RELEASE

#### Immunocore presents new data on KIMMTRAK (tebentafusp-tebn) in metastatic cutaneous (mCM) and uveal melanoma (mUM) at the 2022 American Society of Clinical Oncology (ASCO) Annual Meeting

*Tebentafusp and anti-PDL1 show 1 year overall survival (OS) of approximately 75% in heavily pre-treated mCM compared to benchmark of 55%*

*Characterization of safety and efficacy in patients treated with tebentafusp beyond progression*

*Corticosteroid use for treating adverse events of T cell engagers has no significant impact on efficacy*

(OXFORDSHIRE, England & CONSHOHOCKEN, Penn. & ROCKVILLE, Md., US, 6 June 2022) Immunocore Holdings plc (Nasdaq: IMCR) ("Immunocore" or the "Company"), a commercial-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, autoimmune, and infectious diseases presented updated clinical data from its clinical trials of KIMMTRAK (tebentafusp-tebn) in metastatic cutaneous melanoma (mCM) and metastatic uveal melanoma (mUM) at the 2022 American Society of Clinical Oncology (ASCO) Annual Meeting.

In a Phase 1b trial of tebentafusp in combination with checkpoint inhibitors in mCM, the maximum target doses of tebentafusp (68 mcg) plus durvalumab (20 mg/kg) were well tolerated. In mCM patients who progressed on prior anti-PD(L)1, tebentafusp with durvalumab continues to demonstrate promising overall survival (OS) (1-yr ~75%) compared to recent benchmarks (1-yr ~55%). Cutaneous and uveal melanoma both overexpress gp100, with greater than 80% of cutaneous melanoma tumor cells expressing gp100 by immunohistochemistry (IHC). The pattern of tumor shrinkage and its association with OS observed in mUM are replicated in this mCM study including 37% of patients with any tumor shrinkage of whom 89% lived at least 1-year. 58% of patients with any tumor increase were alive at 1-year, compared to 64% in the Phase 3 study in mUM. These data provide a rationale for a randomized study of tebentafusp monotherapy and in combination with an anti-PD1 in mCM, which the Company plans to start by year end.

"KIMMTRAK (tebentafusp-tebn) was designed to target gp100-positive melanoma, regardless of site of origin, tumor mutational burden or prior therapy. We remain encouraged by the similarities in clinical benefit for this Phase 1 study in metastatic cutaneous melanoma relative to our Phase 3 experience in uveal melanoma and look forward to starting a randomized trial in melanoma by year end," **stated David Berman, Head of Research and Development at Immunocore.** "Additionally, we presented further analysis of KIMMTRAK, the first T cell receptor therapeutic to demonstrate an OS benefit in a randomized study versus investigator's choice, on treatment beyond radiographic progression and the effect of the systemic corticosteroids on efficacy."

In an analysis of the Phase 3 trial of tebentafusp, an OS benefit observed for tebentafusp among mUM patients who have initial radiographic progression demonstrates that radiographic assessment underestimates the benefit. In a post-hoc analysis of OS following initial radiographic progression, continued treatment with tebentafusp was associated with numerically longer OS even after adjusting for the difference in key prognostic variables. Tebentafusp treatment beyond progression was tolerated without new safety signals and, in some patients, was associated with radiological stabilization of target lesions for  $\geq 4$  months following the initial progression.

In another post hoc analysis of the Phase 3 trial, the vast majority patients treated with tebentafusp (84%) either did not require corticosteroids (74%) or only received them on a single day (10%). The most frequent reason for corticosteroid use was an emergent adverse event (AE), including CRS and rash. Corticosteroid use following the pre-specified AE guidelines was not associated with any significant impact on efficacy of tebentafusp.

Presentations and posters will be available for registered attendees on the ASCO website from June 3-7, 2022.

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#### About Uveal Melanoma

Uveal melanoma is a rare and aggressive form of melanoma, which affects the eye. Although it is the most common primary intraocular malignancy in adults, the diagnosis is rare, and up to 50% of people with uveal melanoma will eventually develop metastatic disease. Unresectable or metastatic uveal melanoma typically has a poor prognosis and had no approved treatment until KIMMTRAK.

#### About KIMMTRAK®

KIMMTRAK is a novel bispecific protein comprised of a soluble T cell receptor fused to an anti-CD3 immune-effector function. KIMMTRAK specifically targets gp100, a lineage antigen expressed in melanocytes and melanoma. This is the first molecule developed using Immunocore's ImmTAC technology platform designed to redirect and activate T cells to recognize and kill tumor cells. KIMMTRAK has been granted Breakthrough Therapy Designation, Fast Track designation and orphan drug designation by the Food and Drug Administration (FDA) in the United States, Accelerated Assessment by the European Medicines Agency, and Promising Innovative Medicine (PIM) designation under the UK Early Access to Medicines Scheme for mUM. In January and April 2022, the FDA and the European Commission, respectively, approved KIMMTRAK for the treatment of HLA-A\*02:01-positive adult patients with unresectable or metastatic uveal melanoma.

#### About Phase 3 IMCgp100-202 Trial

The IMCgp100-202 (NCT03070392) is a randomized pivotal trial that evaluated overall survival (OS) of KIMMTRAK (tebentafusp-tebn) compared to investigator's choice (either pembrolizumab, ipilimumab, or dacarbazine) in HLA-A\*02:01-positive adult patients with previously untreated mUM.

KIMMTRAK demonstrated an unprecedented OS benefit with a Hazard Ratio (HR) in the intent-to-treat population favoring KIMMTRAK, HR=0.51 (95% CI: 0.37, 0.71);  $p < 0.0001$ , over investigator's choice (82% pembrolizumab; 13% ipilimumab; 6% dacarbazine).

#### **About ImmTAC® 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 Immunocore**

Immunocore is a commercial-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, autoimmune, and infectious disease. 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 TCR therapeutic, KIMMTRAK (tebentafusp-tebn), has been approved by the U.S. FDA for the treatment of HLA-A\*02:01-positive adult patients with unresectable or metastatic uveal melanoma (mUM) having 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.

#### **Forward Looking Statements**

This press release contains "forward-looking statements" within the meaning of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. All statements, other than statements of historical facts, included in this press release are forward-looking statements. These statements include, but are not limited to, statements regarding the marketing and therapeutic potential of KIMMTRAK to be an effective treatment for patients with mUM and mCM; the expected clinical benefits of KIMMTRAK including extended overall survival benefit; the value proposition of KIMMTRAK in mUM and mCM including expectations regarding the potential market size opportunity; and the future development of tebentafusp, including the initiation, timing, progress and results of future clinical trials including the Company's proposed randomized clinical trial of KIMMTRAK with or without anti-PD1 therapy in patients with metastatic melanoma. 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 impact of the ongoing COVID-19 pandemic and the Omicron variant on the Company's business, strategy clinical trials and financial position; Immunocore's ability to maintain regulatory approval of KIMMTRAK including the timing or likelihood of expansion into additional markets or geographies; its ability to execute its commercialization strategy for KIMMTRAK; its ability to develop, manufacture and commercialize its other product candidates; commercial supply of KIMMTRAK or any future approved products, and launching, marketing and selling of KIMMTRAK or any future approved products; Immunocore's ability and plans in continuing to establish and expand a commercial infrastructure and to successfully launch, market and sell KIMMTRAK in the United States, European Union and other territories; positive results from earlier pre-clinical studies of Immunocore's product candidates may not necessarily be predictive of the results from required later pre-clinical studies and future clinical trials; actions of regulatory agencies, which may affect the initiation, timing and progress of clinical trials or future regulatory approval; Immunocore's ability to obtain, maintain and enforce intellectual property protection for KIMMTRAK or any product candidates it is developing; 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; and the success of Immunocore's current and future collaborations, partnerships or licensing arrangements. These and other risks and uncertainties are described in greater detail in the section titled "Risk Factors" in Immunocore's filings with the Securities and Exchange Commission, including Immunocore's most recent Annual Report on Form 20-F for the year ended December 31, 2021 filed with the Securities and Exchange Commission on March 3, 2022, 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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