



The UK Medicines and Healthcare products Regulatory Agency (MHRA), Australian Therapeutic Goods Administration (TGA) and Health Canada approve KIMMTRAK® (tebentafusp) for the treatment of unresectable or metastatic uveal melanoma

June 8, 2022

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KIMMTRAK is the first and only treatment approved in the UK, Australia, and Canada to treat patients with unresectable or metastatic uveal melanoma

KIMMTRAK demonstrated statistically and clinically meaningful overall survival (OS) benefit, hazard ratio of 0.51, with median OS of almost 22 months

(OXFORDSHIRE, England & CONSHOHOCKEN, Penn. & ROCKVILLE, Md., US, 08 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 today announces that the United Kingdom's Medicines and Healthcare products Regulatory Agency (MHRA), the Therapeutic Goods Administration (TGA) in Australia and Health Canada have granted marketing authorization for KIMMTRAK® (tebentafusp) for the treatment of HLA-A*02:01-positive adult patients with unresectable or metastatic uveal melanoma (mUM).

KIMMTRAK, a gp100 and CD3 ImmTAC® (Immune mobilizing monoclonal TCRs Against Cancer) novel bispecific protein, is the first bispecific T cell engager to receive regulatory approval to treat a solid tumor, and the first and only approved therapy for the treatment of unresectable or metastatic uveal melanoma. Marketing authorization by the MHRA, TGA, and Health Canada follows recent approvals from both the U.S. Food and Drug Administration and the European Commission (EC).

Professor Sir John Bell, Immunocore Chairman and the Regius Professor of Medicine at the University of Oxford, said: "KIMMTRAK is the culmination of more than two decades of scientific discovery. Its approval in the UK, Australia, and Canada, in addition to the United States and European Union, not only represents another important milestone for Immunocore, but a breakthrough for a wholly new category of treatment and for the patients who may experience life-changing benefits, as a result."

Dr. Joe Sacco, Consultant in Medical Oncology at the Clatterbridge Cancer Centre, said: "I am absolutely delighted that KIMMTRAK has now been licensed for the treatment of metastatic uveal melanoma. This has taken a huge commitment over many years from Immunocore, my fellow investigators and the patients who have been enrolled on the studies. This approval is a massive landmark for patients as it will be the first proven standard of care for this rare cancer and provides a significant improvement in survival for patients with this disease."

The approvals in the UK, Australia, and Canada of KIMMTRAK are based on the results of Immunocore's Phase 3 IMCgp100-202 clinical trial, which were published in the September 23, 2021 issue of the *New England Journal of Medicine*. The randomized pivotal trial evaluated overall survival (OS) of KIMMTRAK compared to investigator's choice (either pembrolizumab, ipilimumab, or dacarbazine) in patients with previously untreated mUM. 378 patients were randomized in a 2:1 ratio to either KIMMTRAK or investigator's choice. Data from the trial, the largest Phase 3 trial undertaken in mUM, showed that KIMMTRAK demonstrated unprecedented median OS benefit as a first-line treatment. The OS Hazard Ratio (HR) in the intent-to-treat population favored KIMMTRAK, HR=0.51 (95% CI: 0.37, 0.71); $p < 0.0001$, over investigator's choice (82% pembrolizumab; 13% ipilimumab; 6% dacarbazine). In the clinical trials, across both arms, patients stopped treatment for disease progression, unless the patient was otherwise deriving benefit, or for unacceptable toxicity.

Susanna Daniels, CEO of Melanoma Focus, said: "This is a first for patients with metastatic uveal melanoma, who now have a licensed treatment available. I am thrilled at this turning point for the uveal melanoma community. We are hugely supportive of Immunocore, which has introduced a scheme to permit appropriate patients to be treated with free medicine prior to approval and public reimbursement."

In the randomized Phase 3 trial of KIMMTRAK (tebentafusp), treatment-related adverse reactions were manageable and consistent with the proposed mechanism of action. Among the patients treated with KIMMTRAK, the most common Grade 3 or higher adverse events were rash (18%), pyrexia (4%), and pruritus (5%). In the 245 patients treated with KIMMTRAK, Grade 3 cytokine release syndrome (CRS) occurred in <1% of patients and were generally well-managed. There were no Grade 4 CRS events in the Phase 3 trial.

KIMMTRAK was reviewed under the FDA's Project Orbis initiative, which enabled concurrent review by the health authorities in partner countries that requested participation—including Australia, Canada, and the UK. Australia and Canada are two countries that are part of the Company's multi-territorial agreement with Medison Pharma Ltd. to commercialize KIMMTRAK® (tebentafusp) for the treatment of mUM. The agreement additionally covers twenty markets across Central Eastern Europe, Israel, and New Zealand. Since the opening of the early access program last year, the company admitted patients globally to provide immediate access to KIMMTRAK.

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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 recognise and kill tumor cells. KIMMTRAK has been approved for the treatment of

HLA-A*02:01-positive adult patients with unresectable or metastatic uveal melanoma in the United States, European Union, Canada, Australia, and the United Kingdom.

About Phase 3 IMCgp100-202 Trial

The IMCgp100-202 (NCT03070392) is a randomized pivotal trial that evaluated overall survival (OS) of KIMMTRAK 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).

IMPORTANT SAFETY INFORMATION

Cytokine Release Syndrome (CRS), which may be serious or life-threatening, occurred in patients receiving KIMMTRAK. Monitor for at least 16 hours following first three infusions and then as clinically indicated. Manifestations of CRS may include fever, hypotension, hypoxia, chills, nausea, vomiting, rash, elevated transaminases, fatigue, and headache. CRS occurred in 89% of patients who received KIMMTRAK with 0.8% being grade 3 or 4. Ensure immediate access to medications and resuscitative equipment to manage CRS. Ensure patients are euvolemic prior to initiating the infusions. Closely monitor patients for signs or symptoms of CRS following infusions of KIMMTRAK. Monitor fluid status, vital signs, and oxygenation level and provide appropriate therapy. Withhold or discontinue KIMMTRAK depending on persistence and severity of CRS.

Skin Reactions

Skin reactions, including rash, pruritus, and cutaneous edema occurred in 91% of patients treated with KIMMTRAK. Monitor patients for skin reactions. If skin reactions occur, treat with antihistamine and topical or systemic steroids based on persistence and severity of symptoms. Withhold or permanently discontinue KIMMTRAK depending on the severity of skin reactions.

Elevated Liver Enzymes

Elevations in liver enzymes occurred in 65% of patients treated with KIMMTRAK. Monitor alanine aminotransferase (ALT), aspartate aminotransferase (AST), and total blood bilirubin prior to the start of and during treatment with KIMMTRAK. Withhold KIMMTRAK according to severity.

Embryo-Fetal Toxicity

KIMMTRAK may cause fetal harm. Advise pregnant patients of potential risk to the fetus and patients of reproductive potential to use effective contraception during treatment with KIMMTRAK and 1 week after the last dose.

The most common adverse reactions ($\geq 30\%$) in patients who received KIMMTRAK were cytokine release syndrome, rash, pyrexia, pruritus, fatigue, nausea, chills, abdominal pain, edema, hypotension, dry skin, headache, and vomiting. The most common ($\geq 50\%$) laboratory abnormalities were decreased lymphocyte count, increased creatinine, increased glucose, increased AST, increased ALT, decreased hemoglobin, and decreased phosphate.

For more information, please see full [Summary of Product Characteristics](#) (SmPC) or full U.S. [Prescribing Information](#) (including BOXED WARNING for CRS).

About KIMMTRAKConnect

Immunocore is committed to helping patients who need KIMMTRAK obtain access via our KIMMTRAKConnect program. The program provides services with dedicated nurse case managers who provide personalized support, including educational resources, financial assistance, and site of care coordination. To learn more, visit KIMMTRAKConnect.com or call 844-775-2273.

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.

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; Immunocore's sales and marketing plans; the expected clinical benefits of KIMMTRAK including extended overall survival benefit; expectations regarding the ability to reach patients in a timely manner; the value proposition of KIMMTRAK in mUM and mCM including expectations regarding the potential market size opportunity; physician's feedback and physician interest in prescribing KIMMTRAK as the standard of care for mUM; and the benefits of the Company's global early access program as well as feedback from the participating physicians. 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; its ability to execute its commercialization strategy for KIMMTRAK including the timing or likelihood of expansion into additional markets or

geographies; 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; Immunocore's ability to obtain, maintain and enforce intellectual property protection for KIMMTRAK or any product candidates it is developing; 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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