



Immunocore announces FDA approval of KIMMTRAK® (tebentafusp-tebn) for the treatment of unresectable or metastatic uveal melanoma

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KIMMTRAK is the first and only FDA approved therapy for the treatment of unresectable or metastatic uveal melanoma (mUM)

KIMMTRAK is the first T cell receptor (TCR) therapeutic to receive regulatory approval

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

Company to host an investor call today at 8:30 AM ET

(OXFORDSHIRE, England & CONSHOHOCKEN, Penn. & ROCKVILLE, Md., US, Wednesday, January 26, 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 approval from the United States Food and Drug Administration (FDA) of KIMMTRAK® (tebentafusp-tebn) for the treatment of HLA-A*02:01-positive adult patients with unresectable or metastatic uveal melanoma (mUM).

KIMMTRAK's approval establishes many firsts as the first TCR therapeutic to receive regulatory approval from the FDA, the first bispecific T cell engager to receive regulatory approval from the FDA to treat a solid tumor, and the first and only therapy for the treatment of unresectable or metastatic uveal melanoma to be approved by the FDA.

Bahija Jallal, Chief Executive Officer of Immunocore, said: *"Today's approval of KIMMTRAK is a historic milestone and the culmination of years of dedication by the Immunocore team, patients, and our healthcare partners. Every year in the United States, hundreds of people are diagnosed with metastatic uveal melanoma who, until now, had no approved treatment options. KIMMTRAK is the first therapy to demonstrate a survival benefit to patients with this disease and we are focused on making KIMMTRAK available as quickly as possible.*

Dr. Jallal continues, *"We're also proud to have developed the world's first approved TCR therapeutic, which we believe validates the strength of our platform and opens doors for us to explore further breakthrough discoveries in TCR therapeutics for the treatment of other cancers and diseases with high unmet need."*

"Uveal melanoma is a devastating disease that has historically resulted in death within a year of metastasis for our patients," said John Kirkwood, MD, director of the Melanoma Center at the UPMC Hillman Cancer Center. "The approval of KIMMTRAK (tebentafusp-tebn) represents a major paradigm shift in the treatment of metastatic uveal melanoma, and for the first time offers hope to those with this aggressive form of cancer."

The approval of KIMMTRAK is 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.

"When my husband, Gregg, was diagnosed with metastatic uveal melanoma, it was devastating to learn that there were no treatment options shown to extend life," said Sara Selig, MD, MPH, Co-Founder and Director of the Melanoma Research Foundation's (MRF) CURE OM initiative. "Now, for the first time in the history of this disease, we will soon see extended survival in the next generation of metastatic uveal melanoma patients."

In the randomized Phase 3 trial of KIMMTRAK (tebentafusp-tebn), treatment-related adverse reactions were manageable and consistent with the proposed mechanism. Among the patients treated with KIMMTRAK, the most common Grade 3 or higher adverse reactions 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 or fatal CRS events observed in the Phase 3 trial. A boxed warning is included for CRS as it has the potential to become serious or life-threatening if not managed appropriately.

"Until now, effective treatment options for metastatic uveal melanoma patients were virtually non-existent. The approval of KIMMTRAK represents not only a new therapy but a new hope for the individuals and the families of those diagnosed with the deadliest form of eye cancer," said Kyleigh LiPira, MBA, CEO of the MRF.

The company is ready to commercialize KIMMTRAK and expects to make the product commercially available in the United States within weeks.

KIMMTRAK was granted Breakthrough Therapy Designation for unresectable or metastatic uveal melanoma by the FDA in February 2021. The Biologics License Application (BLA) approval followed review under the Real-Time Oncology Review (RTOR) program, an initiative of the FDA's Oncology Center of Excellence designed for efficient delivery of safe and effective cancer treatments to patients. The approval was granted four weeks ahead of the assigned PDUFA date of February 23, 2022. Immunocore provided an Assessment AID to facilitate FDA review. KIMMTRAK is being reviewed under the FDA's Project Orbis initiative, which enabled concurrent review by the health authorities in partner countries that have requested participation.

The European Medicines Agency (EMA), the United Kingdom's Medicines and Healthcare Regulatory Agency (MHRA), Health Canada, and the Australian Government Department of Health Therapeutic Goods Administration (TGA) have accepted the submission of the Company's Marketing Authorisation Application. Additionally, Immunocore launched a global early access program to make KIMMTRAK readily available to mUM patients. There are currently over 200 patients in 13 countries in the early access program.

Immunocore is committed to helping patients who need KIMMTRAK obtain access via its 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, which will launch later this week, or call 844-775-CARE (2273).

Conference Call Information

Immunocore will host a conference call and webcast today, Wednesday, January 26th at 8:30 AM EST. A live webcast of the conference call will be available under "Events" in the Investor Relations section of Immunocore Holdings' website at www.immunocore.com. To access the live conference call by phone, please dial (US) 877-405-1224 / (Non-US) +1-201-389-0848. The presentation from today's call and the archived webcast will be available on Immunocore's website after the conference call concludes and will be available for 60 days following the call.

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 FDA in the United States, Accelerated Assessment by the EMA, and Promising Innovative Medicine (PIM) designation under the UK Early Access to Medicines Scheme for 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).

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.

Please see [full 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 mobilizing monoclonal TCRs Against Cancer) molecules that are designed to redirect the immune system to recognize and kill cancerous cells. ImmTAC molecules are soluble TCRs engineered to recognize 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 tumors, the ImmTAC mechanism

of action holds the potential to treat hematologic and solid tumors, regardless of mutational burden or immune infiltration, including immune “cold” low mutation rate tumors.

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 for metastatic uveal melanoma (mUM); the expected clinical benefits of KIMMTRAK including extended overall survival benefit; expectations regarding the timing of the commercial launch of KIMMTRAK, the timing of commercial availability and the ability to reach patients in a timely manner; the value proposition of KIMMTRAK in mUM and benefit as an orphan indication including expectations regarding the potential market size opportunity; Immunocore’s sales and marketing plans in the United States; and future development plans of KIMMTRAK, including the timing or likelihood of expansion into additional markets or geographies. 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; its ability to develop, manufacture and commercialize its other product candidates including plans for future development of KIMMTRAK and other product candidates, including the timing or likelihood of expansion into additional markets or geographies; 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; 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, 2020 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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