



Immunocore presents additional ctDNA data from the KIMMTRAK Phase 3 trial at ASCO

June 3, 2023

Early on-treatment ctDNA reduction in stable disease patients treated with KIMMTRAK was associated with longer overall survival

(OXFORDSHIRE, England & CONSHOHOCKEN, Penn. & ROCKVILLE, Md, 3 June 2023) [Immunocore Holdings plc \(Nasdaq: IMCR\)](#), 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, infectious diseases and autoimmune conditions, is presenting today two posters at the 2023 American Society for Clinical Oncology meeting:

- A poster including an analysis of circulating tumor DNA (ctDNA) data from the Phase 3 KIMMTRAK (tebentafusp-tebn) trial in HLA-A*02:01 patients with metastatic uveal melanoma (mUM)
- A trial-in-progress poster describing the design of the Phase 2/3 trial with tebentafusp as monotherapy and in combination with pembrolizumab in HLA-A*02:01 patients with previously treated advanced melanoma.

"We have shown that KIMMTRAK can deliver significant OS benefit to patients with metastatic uveal melanoma, regardless of best RECIST response. We have now validated ctDNA reduction as an early surrogate for OS in two separate clinical trials," said Koustubh Ranade, Vice President of Translational Medicine at Immunocore. "ctDNA reduction is one of the dual endpoints in our ongoing Phase 2/3 trial with tebentafusp in patients with previously treated advanced or metastatic melanoma."

In this analysis of the Phase 3 data for patients with best response of stable disease treated with KIMMTRAK, ctDNA reduction by week 9 was observed in 94% of patients (34/36) with detectable ctDNA at baseline, and this reduction was associated with longer overall survival (OS). These data were consistent with those presented at AACR 2023 in showing that ctDNA reduction by week 9 was strongly associated with improved OS, even in patients with best RECIST response of progressive disease – further indicating that RECIST responses underestimate tebentafusp's clinical benefits, and that early reduction in ctDNA may be a better predictor of long OS than radiographic response.

The Company also presented a trial-in-progress poster for the Phase 2/3 trial that has started randomizing patients with previously treated advanced melanoma, excluding uveal melanoma, who have progressed on an anti-PD1, received prior ipilimumab and, if applicable, received a BRAF kinase inhibitor. Patients will be randomized to one of three arms including tebentafusp, as monotherapy or in combination with an anti-PD1, and a control arm.

Poster details

Title: Early ctDNA reduction may identify patients with stable disease and long OS on tebentafusp

Presenting author: Dan Feng

Session: Melanoma/Skin cancers

Title: A Phase 2/3 trial in progress on tebentafusp as monotherapy and in combination with pembrolizumab in HLA-A*02:01+ patients with previously treated advanced, non-uveal melanoma

Presenting author: Diwakar Davar

Session: Melanoma/Skin cancers (Trial in Progress)

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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 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

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 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, has been approved for the treatment of HLA-A*02:01-positive adult patients with unresectable or metastatic uveal melanoma (mUM) in the United States, European Union, Canada, Australia and the United Kingdom, having demonstrated an overall survival benefit in a randomized Phase 3 clinical trial in mUM, 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. Words such as "may," "can," "will," "believe," "expect," "plan," "anticipate," and similar expressions (as well as other words or expressions referencing future events or circumstances) are intended to identify forward-looking statements. 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 therapeutic potential and expected clinical benefits of our product candidates, including overall survival benefit; expectations that ctDNA reduction from tebentafusp is strongly associated with overall survival benefit; expectations indicating that RECIST responses underestimate tebentafusp's clinical benefits and that ctDNA may be a better predictor of longer OS than radiographic response; expectations regarding the development of Immunocore's pipeline and the design, progress, timing, scope and results of Immunocore's existing and planned clinical trials, including the timing of an OS update from the Phase 3 IMCgp100-202 trial and the trialPhase 2/3 trial with tebentafusp as monotherapy and in combination with pembrolizumab in HLA-A*02:01+ patients with previously treated advanced, non-uveal 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 Immunocore's control.

These risks and uncertainties include, but are not limited to, the impact of worsening macroeconomic conditions and the ongoing and evolving COVID-19 pandemic on Immunocore's business, strategy, clinical trials, financial position and anticipated milestones, including Immunocore's ability to conduct ongoing and planned clinical trials; Immunocore's ability to obtain a clinical supply of current or future product candidates, or commercial supply of KIMMTRAK or any future approved products, including as a result of supply chain disruptions, the COVID-19 pandemic, the war in Ukraine or global geopolitical tension; Immunocore's ability to obtain and maintain regulatory approvals for its product candidates; Immunocore's ability to develop, manufacture and commercialize its product candidates; Immunocore's ability and plans in continuing to establish and expand a commercial infrastructure and to successfully launch, market and sell KIMMTRAK and any future approved products; Immunocore's ability to successfully expand the approved indications for KIMMTRAK or obtain marketing approval for KIMMTRAK in additional geographies in the future; the delay of any current or planned clinical trials, whether due to the COVID-19 pandemic, patient enrollment delays or otherwise; Immunocore's ability to successfully demonstrate the safety and efficacy of its product candidates and gain approval of its product candidates on a timely basis, if at all; competition with respect to market opportunities; unexpected safety or efficacy data observed during pre-clinical studies or clinical trials; actions of regulatory agencies, which may affect the initiation, timing and progress of Immunocore's clinical trials or future regulatory approval; Immunocore's need for and ability to obtain additional funding, on favorable terms or at all, including as a result of worsening macroeconomic conditions such as rising inflation and interest rates, bank failures, volatility in the capital markets and related market uncertainty, the COVID-19 pandemic, the war in Ukraine and global geopolitical tension; Immunocore's ability to obtain, maintain and enforce intellectual property protection for KIMMTRAK or any product candidates it is developing; clinical trial site activation or enrollment rates that are lower than expected; 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, 2022 filed with the Securities and Exchange Commission on March 1, 2023, as well as discussions of potential risks, uncertainties, and other important factors in Immunocore's subsequent filings with the Securities and Exchange Commission. All information in this press release is as of the date of the release, and Immunocore undertakes no duty to update this information, except as required by law.

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