# **IMMUNOCORE**

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December 15, 2022

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Treatment for unresectable or metastatic uveal melanoma, a rare and aggressive form of cancer affecting the eye.

(OXFORDSHIRE, England & CONSHOHOCKEN, Penn. & ROCKVILLE, Md., US, 15 December 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, has been awarded the prestigious Prix Galien France 2022 award in the 'Medicine in Innovative Therapeutics' category, for KIMMTRAK® (tebentafusp), the world's first T cell receptor therapy.

Among a number of breakthroughs, KIMMTRAK is the first bispecific T cell engager to receive regulatory approval to treat a solid tumor, and the only approved therapy for the treatment of unresectable or metastatic uveal melanoma.

"We are honored to receive this prestigious award, which is a reflection of the impact of this novel treatment for patients and the innovative technology behind it," said Bahija Jallal, Immunocore's Chief Executive Officer. "This award is also a tribute to the teams at Immunocore who have taken KIMMTRAK from bench to bedside, and those working on our future therapies that could benefit more patients living with cancer, as well as infectious diseases and autoimmune conditions."

KIMMTRAK was approved by the U.S. Food and Drug Administration; the European Commission; and health authorities in the United Kingdom, Australia and Canada in the first half of 2022. The therapy has been available commercially to patients in France since September 2022.

KIMMTRAK's approved indication, unresectable or metastatic uveal melanoma, is a rare and aggressive form of cancer affecting 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 specifically approved treatment prior to the approval of KIMMTRAK.

The ImmTAX (Immune Mobilizing Monoclonal TCRs Against X disease) platform upon which KIMMTRAK is based harnesses a patient's own immune system to fight cancer and, potentially, infectious diseases. The technology is also being evaluated for its potential to treat patients with autoimmune or inflammatory conditions, through targeted down-modulation of the immune system.

The win crowns a highly successful year for Immunocore, one in which the NASDAQ-listed biotech launched its first medicine after 15 years of research into TCR therapies and delivered updates on key investigational therapies in its pipeline, including for HIV, HBV and PRAME-prevalent cancers.

#### **About Prix Galien**

Founded in France 50 years ago by pharmacist Roland Mehl in honor of Galen, the father of medical science and modern pharmacology, the Prix Galien supports, recognizes and awards the efforts of scientists, researchers and companies committed to advancing medical innovation with the power to change the human condition. Worldwide, the Prix Galien is regarded as the equivalent of the Nobel Prize in biopharmaceutical research.

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## **NOTES FOR EDITORS**

#### **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. The Company'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 in the United States, European Union, Canada, Australia, and the United Kingdom.

## **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," "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 marketing and therapeutic potential of KIMMTRAK for unresectable or mUM; the expected clinical benefits of KIMMTRAK and the Company's other product candidates; the value proposition of Immunocore's product candidates, including KIMMTRAK in mUM and its benefit as an orphan indication, including expectations regarding the development of metastatic disease in patients who have uveal melanoma and the typical prognosis for unresectable or mUM; and statements regarding the development of Immunocore's pipeline. Any forward-looking statements are based on management's current expectations and beliefs of future events and are subject to a number of risks and uncertainties that could cause actual events or 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 and evolving COVID-19 pandemic on the

Company's business, financial position, strategy 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 the COVID-19 pandemic, war in Ukraine or global geopolitical tension; Immunocore's ability to obtain and maintain regulatory approval of its product candidates, including KIMMTRAK; 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 preclinical studies or clinical trials; actions of regulatory agencies, which may affect the initiation, timing and progress of 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 rising inflation, interest rates and general market conditions, and the impacts thereon of the COVID-19 pandemic, 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; 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.

#### **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 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.

#### **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 (≥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 (≥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).

# **CONTACT INFORMATION**

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