

## Immunocore Reports First Quarter 2022 Financial Results and Provides Business Update

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*KIMMTRAK® (tebentafusp-tebn) approved in the United States and European Union for the treatment of unresectable or metastatic uveal melanoma*

*Promotional launches and sales of KIMMTRAK ongoing in U.S., Germany, and France*

*All patients in U.S. early access program successfully transitioned to commercial supply in Q1*

*Plan to report Phase 1 data from ImmTAC clinical candidates targeting PRAME (3Q 2022) and MAGE-A4 (4Q 2022) in multiple solid tumors this year*

*Net KIMMTRAK and pre-product revenues of £10.5 million (\$13.8 million) in Q1 2022 and net cash position of approximately \$271 million as of March 31, 2022*

(OXFORDSHIRE, England & CONSHOHOCKEN, Penn. & ROCKVILLE, Md., US, 11 May 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 announced its financial results for the first quarter ended March 31, 2022 and provided a business update.

**Bahija Jallal, Chief Executive Officer of Immunocore, said:** “This has been an exciting start to the year for Immunocore, during which we have continued to establish ourselves as a pioneer in TCR therapeutics. Our gp100 and CD3 targeting ImmTAC, KIMMTRAK, the first in this new class of TCR treatments for cancer and other diseases, has now received regulatory approval for the treatment of unresectable or metastatic uveal melanoma in the United States and European Union. We look forward later this year to exploring KIMMTRAK in cutaneous melanoma and to learning more about the broader potential of our TCR platform with data readouts from our programs targeting PRAME and MAGE.”

**Ralph Torbay, Head of Commercial, said:** “KIMMTRAK is now approved in 30 countries globally. In the U.S., we have successfully transitioned all early access patients onto commercial product and our team is working closely with healthcare providers to change medical practice and rapidly identify new eligible patients who could benefit from KIMMTRAK. Furthermore, we were delighted that the U.S. National Comprehensive Cancer Network (NCCN) has added KIMMTRAK to the Clinical Practice Guidelines as a Category 1 treatment for unresectable or metastatic uveal melanoma, effectively positioning KIMMTRAK as a standard of care. In Europe, KIMMTRAK is now being promoted in Germany and France, and we expect launches to follow in additional priority countries.”

### First Quarter 2022 Highlights (including post-period)

#### **KIMMTRAK® (tebentafusp-tebn)**

In January, the U.S. Food and Drug Administration (FDA) approved KIMMTRAK (tebentafusp-tebn) for the treatment of patients with unresectable or metastatic uveal melanoma (mUM). KIMMTRAK is the first TCR therapeutic, the first bispecific T cell engager to treat a solid tumor, and the first and only therapy for the treatment of unresectable or mUM to receive approval from the FDA.

In February, the Committee for Medicinal Products for Human Use, or CHMP, of the European Medicines Agency, or the EMA, adopted a positive opinion recommending the approval of KIMMTRAK for the treatment of HLA-A\*02:01-positive adult patients with unresectable or mUM.

In March, Immunocore successfully transitioned all patients from U.S. early access program (EAP) onto commercial supply. KIMMTRAK was commercially available less than four weeks after FDA approval.

For the first quarter ended, March 31, 2022, Immunocore reported combined net KIMMTRAK and pre-product revenues of £10.5 million (or \$13.8 million). U.S. net product revenue from the sale of KIMMTRAK in the first quarter was £7.7 million (or \$10.1 million), this is largely due to the successful transition of patients from the EAP onto commercial supply. Pre-product revenue in France for the first quarter was £2.8 million (or \$3.7 million).

In April, the EC approved KIMMTRAK (tebentafusp) for the treatment of HLA-A\*02:01-positive adult patients with unresectable or metastatic uveal melanoma (mUM). With this approval, KIMMTRAK has received marketing authorisation in all European Union, or EU, member states, and following completion of related national procedures, will also be eligible for sale in Iceland, Liechtenstein, and Norway. We plan to pursue regulatory approval for the marketing authorization of KIMMTRAK in all 27 member states of the EU. Following the approval of KIMMTRAK in the EU, the Company plans to transition patients from the early access programs. There are currently over 130 patients on EAP in the EU and UK.

In April, KIMMTRAK was added as a recommended Category 1 treatment in the latest National Comprehensive Cancer Network® (NCCN®) Clinical Practice Guidelines in Oncology for metastatic uveal melanoma (mUM). NCCN publishes evidence-based guidelines that are followed by many healthcare professionals in the U.S. and globally.

In May, the Company began the commercial launch of KIMMTRAK in Germany. The company has begun transitioning patients from the EAP onto commercial supply and enabling the identification of new patients.

### Anticipated Upcoming Milestones

#### **KIMMTRAK**

- Q4 2022 – start randomized clinical trial in metastatic cutaneous melanoma (mCM)

### *ImmTAC pipeline*

- Q3 2022 – report initial data from IMC-F106C (PRAME) Phase 1 trial in multiple solid tumors
- Q4 2022 – report complete data from IMC-C103C (MAGE-A4) Phase 1 trial in multiple solid tumors and initial data from ovarian expansion arm

### *ImmTAV pipeline*

- Q2 2022 – dose first patient in IMC-M113V Phase 1 study in HIV

## **Financial Results**

Basic and diluted loss per share was £0.37 (or \$0.48) for the three months ended March 31, 2022 compared to £0.76 for the three months ended March 31, 2021. Total operating loss for the three months ended March 31, 2022 was £16.5 million (or \$21.6 million) compared to £31.9 million for the same period last year.

Total revenue for the three months ended March 31, 2022 was £22.5 million (or \$29.6 million), as compared to £8.3 million for the three months ended March 31, 2021. Revenue in the three months ended March 31, 2022 consisted of net product revenue from the sale of KIMMTRAK in the United States, net pre-product revenue under a compassionate use and an early access program in France, and collaboration revenue. Revenue in the three months ended March 31, 2021 was generated solely from the Group's collaborations.

Net product revenue from the sale of KIMMTRAK in the three months ended March 31, 2022 was £7.7 million (or \$10.1 million) following FDA approval in January 2022. This is largely due to the successful transition of patients from the EAP in the U.S. to commercial supply. Net pre-product revenue for the first quarter was £2.8 million (or \$3.7 million). Collaboration revenue increased by £3.7 million to £12.0 million (or \$15.7 million) in the three months ended March 31, 2022 compared to £8.3 million for the three months ended March 31, 2021, primarily due to the recognition of remaining revenue under the Lilly Collaboration following termination of the agreement in the three months ended March 31, 2022.

For the three months ended March 31, 2022, our research and development ("R&D") expenses were £18.6 million (or \$24.4 million), respectively, as compared to £19.9 million for the three months ended March 31, 2021. The reduction was driven by lower R&D costs incurred in relation to tebentafusp following the launch of KIMMTRAK.

For the three months ended March 31, 2022, our administrative expenses were £20.1 million (or \$26.4 million), respectively, compared to £20.2 million for the three months ended March 31, 2021.

Cash and cash equivalents were £205.9 million or approximately \$270.7 million as of March 31, 2022 compared to £237.9 million as of December 31, 2021.

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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 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](http://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 commercial launch of KIMMTRAK in the United States, Germany and France as well as in other EU member states; Immunocore's sales and marketing plans in the United States, Germany and France and the successful transition of patients on early access onto commercial supply; the timing of commercial availability of KIMMTRAK in additional countries 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; physician's feedback and physician interest in prescribing KIMMTRAK as the standard of care for mUM; Immunocore's efforts on expanding patients' access to medicine; future development plans of KIMMTRAK, including the timing or likelihood of expansion into additional markets or geographies; and expectations regarding the timing of the availability of future clinical trial results including from PRAME and MAGE-A4 clinical trials in multiple solid tumors. 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; 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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## Condensed Consolidated Statement of Loss

### Comparison of the Three Months Ended March 31, 2022 and 2021

	Three Months Ended March 31,		
	2022		2021
	\$'000	£'000	£'000
Product revenue, net	10,103	7,682	—
Pre-product revenue, net	3,721	2,829	—
Collaboration revenue	15,734	11,963	8,270
<b>Total revenue</b>	<b>29,558</b>	<b>22,474</b>	<b>8,270</b>
Cost of product revenue	(326)	(248)	—
Research and development expenses	(24,438)	(18,581)	(19,885)
Selling and administrative expenses	(26,443)	(20,106)	(20,184)
Net other operating income / (expense)	1	1	(82)
<b>Operating loss</b>	<b>(21,648)</b>	<b>(16,460)</b>	<b>(31,881)</b>
Finance income	13	10	22
Finance costs	(1,753)	(1,333)	(1,860)
<b>Non-operating expense</b>	<b>(1,740)</b>	<b>(1,323)</b>	<b>(1,838)</b>
<b>Loss before taxes</b>	<b>(23,388)</b>	<b>(17,783)</b>	<b>(33,719)</b>
Income tax credit	2,177	1,655	4,681
<b>Loss for the period</b>	<b>(21,211)</b>	<b>(16,128)</b>	<b>(29,038)</b>

### Condensed Consolidated Statement of Cash Flows for Each Period Presented:

	Three Months Ended March 31,		
	2022	2022	2021
	\$'000	£'000	£'000
Cash and cash equivalents at beginning of year	312,868	237,886	129,716
Net cash flows used in operating activities	(40,552)	(30,833)	(25,979)
Net cash flows (used in) / from investing activities	(175)	(133)	25
Net cash flows (used in) / from financing activities	(1,752)	(1,332)	209,373
Net foreign exchange difference on cash held	349	265	(52)
Cash and cash equivalents at end of period	<u>270,738</u>	<u>205,853</u>	<u>313,083</u>

### Condensed Consolidated Statement of Financial Position as at:

	March 31,	December 31,
	2022	2021
	£'000	£'000
<b>Non-current assets</b>		
Property, plant and equipment	7,849	8,944
Right of use assets	22,199	22,593
Other non-current assets	5,955	4,935
Deferred tax asset	2,650	2,575
<b>Total non-current assets</b>	<b>38,653</b>	<b>39,047</b>
<b>Current assets</b>		
Inventory	496	—
Trade and other receivables	25,746	15,208
Tax receivable	11,289	9,632
Cash and cash equivalents	205,853	237,886
<b>Total current assets</b>	<b>243,384</b>	<b>262,726</b>
<b>Total assets</b>	<b>282,037</b>	<b>301,773</b>

<b>Equity</b>		
Share capital	88	88
Share premium	212,499	212,238
Foreign currency translation reserve	294	89
Other reserves	386,167	386,167
Share-based payment reserve	61,770	54,357
Accumulated deficit	(497,520)	(481,392)
<b>Total equity</b>	<b>163,298</b>	<b>171,547</b>
<b>Non-current liabilities</b>		
Interest-bearing loans and borrowings	38,370	37,226
Deferred revenue	2,136	6,408
Lease liabilities	25,043	25,355
Provisions	70	57
<b>Total non-current liabilities</b>	<b>65,619</b>	<b>69,046</b>
<b>Current liabilities</b>		
Trade and other payables	34,695	35,436
Deferred revenue	17,089	24,450
Lease liabilities	1,294	1,255
Provisions	42	39
<b>Total current liabilities</b>	<b>53,120</b>	<b>61,180</b>
<b>Total liabilities</b>	<b>118,739</b>	<b>130,226</b>
<b>Total equity and liabilities</b>	<b>282,037</b>	<b>301,773</b>