



## Immunocore Reports Second Quarter 2021 Financial Results and Provides Business Update

August 11, 2021

### PRESS RELEASE

#### Immunocore Reports Second Quarter 2021 Financial Results and Provides Business Update

*Biologics License Application (BLA) submission for tebentafusp in metastatic uveal melanoma remains on track for completion in Q3; FDA has granted tebentafusp Real Time Oncology Review (RTOR) and the application will be part of the Project Orbis initiative*

*Submission of a Market Authorization Application (MAA) to the European Medicines Agency (EMA), and the United Kingdom's Medicines and Healthcare Regulatory Agency (MHRA) accelerated to Q3; EMA granted tebentafusp accelerated assessment procedure for this MAA*

*Dose escalation of IMC-C103C targeting MAGE-A4 and IMC-F106C targeting PRAME continues as planned; initial Phase 1 MAGE-A4 data planned for Q4*

*Cash position of approximately \$385 million as of June 30, 2021*

(OXFORDSHIRE, England & CONSHOHOCKEN, Penn. & ROCKVILLE, Md., US, 11 August 2021) [Immunocore](#) Holdings plc (Nasdaq: IMCR), a late-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 and autoimmune disease, today announced its financial results for the quarter and six months ended June 30, 2021 and provides a portfolio update.

Immunocore's recent and second quarter highlights include the acceleration of tebentafusp regulatory submissions in the EU and UK; continued dose escalation of MAGE-A4 and PRAME targeting ImmTACs<sup>®</sup>; and the initiation of a single ascending dose trial for its ImmTAV<sup>®</sup> bispecific molecule for chronic hepatitis B (HBV).

**Bahija Jallal, Chief Executive Officer of Immunocore, said:** *"The team at Immunocore is focused on bringing our pioneering science to patients as quickly as possible. We remain on track to complete the tebentafusp BLA submission in the US in the third quarter and are pleased to have accelerated our submissions in Europe, while also initiating our global early access program to make tebentafusp available to patients who need it now."*

*"With the positive phase 3 results for tebentafusp in metastatic uveal melanoma, we now have demonstrated the first ever overall survival benefit for any TCR therapeutic," said David Berman, Head of Research and Development. "Our Phase 1 programs targeting MAGE-A4 and PRAME continue to dose escalate, with both now at biologically active doses. The start of our first clinical trial in chronic hepatitis B further highlights our confidence in the potential of our ImmTAX platform across a broad range of indications including cancer and infectious disease."*

#### Second Quarter 2021 Highlights (including post-period)

##### **Tebentafusp**

In July, the European Medicines Agency (EMA) granted tebentafusp accelerated assessment procedure for this Marketing Authorization Application (MAA). Accelerated assessment potentially reduces the time frame for the EMA Committee for Medicinal Products for Human Use (CHMP) and Committee for Advanced Therapies (CAT) to review a MAA for an Advanced Therapy Medicinal Product (ATMP). The U.S. Food and Drug Administration (FDA) will review the Biologics License application (BLA) for tebentafusp (IMCgp100) under the Real-Time Oncology Review (RTOR) pilot program, an initiative of the FDA's Oncology Center of Excellence designed to expedite the delivery of safe and effective cancer treatments to patients. Tebentafusp is also being reviewed under the FDA's Project Orbis initiative, which enables concurrent review by the health authorities in partner countries that have requested participation. Previously, the FDA has granted Breakthrough Therapy Designation (BTD) to tebentafusp (IMCgp100) for the treatment of HLA-A\*02:01-positive adult patients with unresectable or metastatic uveal melanoma (mUM).

In June, the Company presented a subset analysis from the Phase 3 study exploring the overall survival benefit from tebentafusp in patients with best RECIST\* response of progressive disease (PD) at the American Society of Clinical Oncology (ASCO) Annual Meeting. In patients with a best response of PD in the Phase 3 trial, the overall survival (OS) was superior for the tebentafusp arm versus the investigator's choice arm with a hazard ratio (HR) of 0.43 (95% CI 0.27-0.68). More than half of tebentafusp patients with best response PD were treated beyond initial progression and no new safety signals were observed. In addition, analysis from the Phase 2 tebentafusp trial suggests that at least one-third of patients on tebentafusp with a best response of PD have a reduction in circulating tumor DNA and that this may be associated with longer OS.

In April, the Company launched a global early access program for tebentafusp in mUM.

In April, the Company's Phase 3 data of tebentafusp in mUM was also the subject of an oral presentation in the Phase 3 clinical trials plenary session at the AACR Virtual Annual Meeting 2021. Tebentafusp demonstrated a statistically significant and clinically meaningful improvement in overall survival (OS) as a first-line treatment in mUM. In the intent-to-treat population, tebentafusp demonstrated a median overall survival of 21.7 months compared to 16.0 months for investigator's choice and with 73% of patients alive at 1 year for tebentafusp vs. 58% for investigator's choice. The OS Hazard Ratio (HR) favored tebentafusp, HR=0.51 (95% CI: 0.37, 0.71); p< 0.0001, over investigator's choice (82% pembrolizumab; 12% ipilimumab; 6% dacarbazine). In addition, tebentafusp resulted in a statistically significant longer PFS. Treatment-related adverse events were manageable and consistent with the proposed mechanism.

The Company remains on track to complete submission of a BLA to the FDA in the third quarter of 2021. Additionally, the Company has accelerated the submission of a MAA to the EMA, and the United Kingdom's Medicines and Healthcare Regulatory Agency, or MHRA, to the third quarter of 2021.

##### **Additional Clinical Programs**

### *IMC-C103C targeting MAGE-A4*

In the second quarter, the Company continued to dose escalate IMC-C103C, an ImmTAC molecule targeting an HLA-A\*02:01 MAGE-A4 antigen, in a first-in-human, Phase 1/2 dose escalation trial in patients with solid tumor cancers including non-small-cell lung cancer (NSCLC), gastric, head and neck, ovarian and synovial sarcoma. As of June 30, 2021, the Company has enrolled 39 patients in the Phase 1 study. Early pharmacodynamic data indicate that IMC-C103C monotherapy is demonstrating biological activity at the doses currently under evaluation. The Company plans to report this initial Phase 1 data in the fourth quarter of 2021.

### *IMC-F106C targeting PRAME*

In the second quarter, the Company continued to dose escalate IMC-F106C, an ImmTAC molecule targeting an HLA-A\*02:01 PRAME antigen, in a first-in-human, Phase 1/2 dose escalation trial in patients with multiple solid tumor cancers. PRAME is overexpressed in many solid tumors including NSCLC, SCLC, endometrial, ovarian, melanoma and breast cancers. As of June 30, 2021, the company has enrolled 23 patients in the Phase 1 study. Early pharmacodynamic data indicate that IMC-F106C monotherapy is demonstrating biological activity at the doses currently under evaluation. The Company plans to report this initial Phase 1 data in mid-2022.

### *IMC-I109V targeting HBV*

In the second quarter, the Company initiated dosing in the IMC-I109V global Phase 1 single ascending dose trial. IMC-I109V is the first candidate in development using Immunocore's immune -mobilising monoclonal T cell receptors against virus (ImmTAV®) platform to enter clinical trials. IMC-I109V targets a conserved Hepatitis B virus (HBV) envelope antigen and is being developed as a potential functional cure.

## **Financial Results**

Basic and diluted loss per share was £0.75 or \$1.04 for the three months ended June 30, 2021 as compared to an adjusted £0.63 for the three months ended June 30, 2020. Basic and diluted loss per share was £1.51 or \$2.08 for the six months ended June 30, 2021 compared to an adjusted £1.39 for the six months ended June 30, 2020. Total operating loss for the three months ended June 30, 2021 was £34.5 million or \$47.6 million compared to £20.5 million for the same period last year, largely due to an increase in employee costs associated with non-cash share-based payment charge. Total operating loss for the six months ended June 30, 2021 was £66.4 million or \$91.6 million compared to £42.6 million for the same period last year, largely due to an increase in employee costs associated with non-cash share-based payment charge.

For the three and six months ended June 30, 2021, revenue from collaboration agreements was £5.7 million or \$7.9 million and £14.0 million or \$19.3 million, respectively, as compared to £7.8 million and £16.0 million, respectively, for the three and six months ended June 30, 2020. For the three and six months ended June 30, 2021, research and development expenses were £16.5 million or \$22.7 million and £36.4 million or \$50.2 million, respectively, as compared to £16.4 million and £37.2 million, respectively, for the three and six months ended June 30, 2020. For the three and six months ended June 30, 2021, administrative expenses were £23.8 million or \$32.9 million and £44.0 million or \$60.7 million, respectively, compared to £12.3 million and £21.9 million respectively, for the three and six months ended June 30, 2020 including a £5.1 million and £13.0 million increase, respectively, in the non-cash share-based payment charge.

Cash and cash equivalents are £278.9 million or approximately \$385 million as of June 30, 2021 compared to £129.7 million as of December 31, 2020.

##

## **About Tebentafusp**

Tebentafusp is a novel bispecific protein comprised of a soluble T cell receptor fused to an anti-CD3 immune-effector function. Tebentafusp specifically targets gp100, a lineage antigen expressed in melanocytes and melanoma, and is the first molecule developed using Immunocore's ImmTAC technology platform designed to redirect and activate T cells to recognise and kill tumour cells. Tebentafusp has been granted Breakthrough Therapy Designation, Fast Track designation and orphan drug designation by the FDA in the United States and Promising Innovative Medicine (PIM) designation under the UK Early Access to Medicines Scheme for metastatic uveal melanoma. The European Medicine Agency (EMA) has granted the Tebentafusp Marketing Authorization Application (MAA) for an Accelerated Assessment procedure based on the Committee for Medicinal Products for Human Use (CHMP) agreement that tebentafusp is a product of major interest for public health and therapeutic innovation. Tebentafusp is also being reviewed under the FDA's Project Orbis initiative, which enables concurrent review by the health authorities in partner countries that have requested participation. For more information about enrolling tebentafusp clinical trials for metastatic uveal melanoma, please visit [ClinicalTrials.gov](https://ClinicalTrials.gov) (NCT03070392).

## **About Immunocore**

Immunocore is a late-stage biotechnology company pioneering the development of a novel class of TCR bispecific immunotherapies called ImmTAX – Immune mobilising monoclonal TCRs Against X disease – designed to treat a broad range of diseases, including cancer, infectious and autoimmune. 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 therapeutic candidate, tebentafusp, has 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 Private Securities Litigation Reform Act of 1995, including, but are not limited to, statements regarding the Company's business strategy including its proposed regulatory plans for tebentafusp, the efficacy, safety and therapeutic potential of tebentafusp, the planned timing of a complete BLA submission for tebentafusp for the treatment of mUM in the third quarter of 2021, the potential approval and commercial launch of tebentafusp for mUM, the design, progress, timing, scope and results of the Company's clinical trials including IMC-C103C, IMC-F106C and IMC-I109V, the anticipated achievement of upcoming clinical milestones, the potential benefit of Breakthrough Therapy Designation or Orphan Drug Designation for tebentafusp, and the Company's anticipated cash runway. 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 impacts of the COVID-19 pandemic on the Company's business, clinical trials and financial position; unexpected safety or efficacy data observed during preclinical studies or clinical trials; clinical trial site activation or enrollment rates that are lower than expected; the risk that initial or interim results from a clinical trial may not be predictive of the final results of the trial or the results of future trials; changes in expected or existing competition; changes in the regulatory environment; and the uncertainties and timing of the regulatory approval process. For a discussion of other risks and uncertainties, and other important factors, any of which could cause our actual results to differ from those contained in the forward-looking statements, see the section titled "Risk Factors" in the Company's 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.

#### CONTACT:

##### Immunocore

Debra Nielsen, Head of Communications

T: +1 (610) 368-8602

E: [debra.nielsen@immunocore.com](mailto:debra.nielsen@immunocore.com)

Follow on Twitter: @Immunocore

##### Consilium Strategic Communications (corporate and financial)

Mary-Jane Elliott/ Chris Welsh/ Jessica Hodgson

T: +44 (0)203 709 5700

E: [immunocore@consilium-comms.com](mailto:immunocore@consilium-comms.com)

##### Investor Relations

Clayton Robertson, Head of Investor Relations

T: +1 215-384-4781

E: [ir@immunocore.com](mailto:ir@immunocore.com)

#### Consolidated Statement of Loss

##### Comparison of the Three Months Ended June 30, 2021 and 2020:

	Three Months Ended June 30,		
	2021		2020
	\$000	£000	£000
Revenue	7,915	5,733	7,787
Research and development expenses	(22,740)	(16,471)	(16,378)
Administrative expenses	(32,860)	(23,801)	(12,250)
Net other operating income	55	40	346
<b>Operating loss</b>	<b>(47,630)</b>	<b>(34,499)</b>	<b>(20,495)</b>
Finance income	17	12	222
Finance costs	(1,778)	(1,288)	(635)
<b>Non-operating expense</b>	<b>(1,761)</b>	<b>(1,276)</b>	<b>(413)</b>
<b>Loss before taxes</b>	<b>(49,391)</b>	<b>(35,775)</b>	<b>(20,908)</b>
Income tax credit	3,884	2,813	3,691
<b>Loss for the period</b>	<b>(45,507)</b>	<b>(32,962)</b>	<b>(17,217)</b>
<b>Basic and diluted loss per share</b>	<b>\$(1.04)</b>	<b>(0.75)</b>	<b>(0.63)</b>

##### Comparison of the Six Months Ended June 30, 2021 and 2020:

	Six Months Ended June 30,		
	2021		2020
	\$000	£000	£000
Revenue	19,333	14,003	16,042
Research and development expenses	(50,193)	(36,356)	(37,157)
Administrative expenses	(60,726)	(43,985)	(21,855)
Net other operating (expense) / income	(58)	(42)	356
<b>Operating loss</b>	<b>(91,644)</b>	<b>(66,380)</b>	<b>(42,614)</b>
Finance income	47	34	1,605
Finance costs	(4,346)	(3,148)	(1,702)
<b>Non-operating expense</b>	<b>(4,299)</b>	<b>(3,114)</b>	<b>(97)</b>
<b>Loss before taxes</b>	<b>(95,943)</b>	<b>(69,494)</b>	<b>(42,711)</b>
Income tax credit	10,346	7,494	6,855
<b>Loss for the period</b>	<b>(85,597)</b>	<b>(62,000)</b>	<b>(35,856)</b>
<b>Basic and diluted loss per share</b>	<b>\$(2.08)</b>	<b>(1.51)</b>	<b>(1.39)</b>

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

	Six Months Ended June 30,		
	2021	2021	2020
	\$000	£000	£000
		(unaudited)	
Cash and cash equivalents at beginning of year	179,085	129,716	73,966
Net cash flows used in operating activities	(80,867)	(58,575)	(40,645)
Net cash flows from / (used in) investing activities	61	44	(1,684)
Net cash flows from financing activities	286,834	207,761	25,054
Net foreign exchange difference on cash held	(105)	(76)	118
Cash and cash equivalents at end of period	<u>385,008</u>	<u>278,870</u>	<u>56,809</u>

**Consolidated Statements of Financial Position for Each Period Presented:**

	June 30,	December 31,
	2021	2020
	£'000	£'000
<b>Non-current assets</b>		
Property, plant and equipment	10,988	13,754
Right of use assets	22,391	23,093
Investment in sub-lease	470	776
Other non-current financial assets	5,476	4,410
Deferred tax asset	2,192	2,230
<b>Total non-current assets</b>	<u>41,517</u>	<u>44,263</u>
<b>Current assets</b>		
Trade and other receivables	12,198	10,280
Tax receivable	20,428	12,935
Cash and cash equivalents	278,870	129,716
<b>Total current assets</b>	<u>311,496</u>	<u>152,931</u>
<b>Total assets</b>	<u>353,013</u>	<u>197,194</u>
<b>Equity</b>		
Share capital	88	64
Share premium	211,286	-
Foreign currency translation reserve	33	163
Other reserves	386,167	386,167
Share-based payment reserve	36,434	18,821
Accumulated deficit	(411,869)	(349,869)
<b>Total equity</b>	<u>222,139</u>	<u>55,346</u>
<b>Non-current liabilities</b>		
Interest-bearing loans and borrowings	36,135	36,654
Deferred liabilities	14,953	24,868
Lease liabilities	24,923	25,190
Provisions	175	138
<b>Total non-current liabilities</b>	<u>76,186</u>	<u>86,850</u>
<b>Current liabilities</b>		
Interest-bearing loans and borrowings	546	---
Trade and other payables	27,027	25,728
Deferred liabilities	25,395	27,118
Lease liabilities	1,605	2,043
Provisions	115	109
<b>Total current liabilities</b>	<u>54,688</u>	<u>54,998</u>
<b>Total liabilities</b>	<u>130,874</u>	<u>141,848</u>
<b>Total equity and liabilities</b>	<u>353,013</u>	<u>197,194</u>