



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

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### PRESS RELEASE

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*Biologics License Application (BLA) and Marketing Authorisation Application (MAA) submissions accepted for tebentafusp in metastatic uveal melanoma; FDA set a PDUFA date of February 23, 2022*

*Over 150 patients have accessed tebentafusp through the global early access program across 14 countries*

*Dose escalation of IMC-C103C targeting MAGE-A4 continues as planned; investor call planned for initial Phase 1 MAGE-A4 data scheduled for presentation at the ESMO IO Congress in December*

*Cash position of approximately \$346 million as of September 30, 2021*

(OXFORDSHIRE, England & CONSHOHOCKEN, Penn. & ROCKVILLE, Md., US, 10 November 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 nine months ended September 30, 2021 and provides a business update.

Immunocore's recent and third quarter highlights include the acceptance of tebentafusp regulatory submissions in the US, EU and UK; the publication of Phase 3 tebentafusp data in the *New England Journal of Medicine*; and the continued dose escalation of MAGE-A4 and PRAME targeting ImmTACs<sup>®</sup> with data to be presented from IMC-C103C targeting MAGE-A4 at the European Society of Medical Oncology Immuno-Oncology Congress in December of this year (ESMO IO Congress).

**Bahija Jallal, Chief Executive Officer of Immunocore, said:** *"We continue to be encouraged by the interest in our tebentafusp data in metastatic uveal melanoma, including the publication of our Phase 3 data in the New England Journal of Medicine. We have now activated our early access program in fourteen countries and have treated over 150 patients with metastatic uveal melanoma over the last six months. As we advance our ImmTAC programs in other solid tumors, we look forward to continuing to update on our progress at upcoming medical meetings."*

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

##### **Tebentafusp**

Earlier this month, the Company presented new clinical data from the metastatic uveal melanoma (mUM) tebentafusp monotherapy program and a Phase 1b study of tebentafusp in combination with durvalumab (anti-PDL1) and/or tremelimumab (anti-CTLA4) in metastatic cutaneous melanoma (mCM) in poster presentations at the Society for Immunotherapy of Cancer (SITC) 36<sup>th</sup> Annual Meeting. In a phase 1b trial in mCM of tebentafusp in combination with checkpoint inhibitors, in which the majority of patients had previously received prior anti-PD(L)1 treatments, the maximum target doses of tebentafusp (68 mcg) plus durvalumab (20 mg/kg) with and without tremelimumab (1 mg/kg) were tolerated in both doublet and triplet arms of the study. Preliminary evidence of tebentafusp clinical activity in mCM patients who had prior anti-PD(L)1 therapy, currently an unmet medical need, included 1-year overall survival (OS) rate of 76%. In mCM patients who were refractory (defined as best response of progressive disease) to prior anti-PD(L)1, the 1-year OS rate was 61%. In addition, the Company presented a new analysis of baseline gp100 protein tumor expression by immunohistochemistry of tumor biopsies from the phase 2 and phase 3 tebentafusp monotherapy mUM trials, where OS benefit was observed for both high and low gp100 protein tumor expression. Four additional posters depicting new analyses from tebentafusp in metastatic uveal melanoma, as well as the Company's proprietary soluble TCR bispecific ImmTAC platform were also accepted for presentation at the upcoming SITC 36<sup>th</sup> Annual Meeting and will be made available for on-demand viewing throughout the meeting.

In October, the Company announced an exclusive multi-regional agreement for Medison Pharma Ltd. to help seek regulatory authorization and commercialize Immunocore's tebentafusp (IMCgp100), for the treatment of patients with mUM, in Canada, twenty markets across Central Eastern Europe and Israel. Under the agreement, Medison Pharma would also provide assistance with commercialization activities, assuming regulatory approval is received.

In the third quarter, the Australian Government Department of Health granted tebentafusp Orphan Drug Designation. Additionally, the Australian Government Department of Health has accepted the Marketing Application for tebentafusp in mUM, and the company (through the Adjutor Healthcare Party Ltd.) has also received a Priority Review of its application for approval.

In September, *The New England Journal of Medicine* (NEJM) published online data from the IMCgp100-202 Phase 3 randomized clinical trial in mUM where the OS Hazard Ratio (HR) in the intent-to-treat population favored tebentafusp, HR=0.51 (95% CI: 0.37, 0.71). The NEJM paper concluded that tebentafusp prolonged OS compared to investigator's choice in previously untreated mUM.

In September, the Company presented new data and analysis from tebentafusp at the ESMO Congress. The findings presented in an oral presentation, by Alexander N. Shoushtari MD, medical oncologist at Memorial Sloan Kettering Cancer Center, demonstrated that 70% of evaluable patients had a reduction in circulating tumor DNA (ctDNA) by Week 9 and the degree of reduction was strongly associated with OS.

In September, the Company announced the United Kingdom's Medicines and Healthcare products Regulatory Agency has accepted a MAA seeking the approval of tebentafusp for the treatment of patients with mUM.

In August, the U.S. Food and Drug Administration (FDA) accepted for review Immunocore's BLA for tebentafusp. The FDA has granted Priority Review to the Company's BLA submission, a designation for drugs which, if approved, may provide significant improvements in the safety and effectiveness of the treatment of serious conditions. Priority Review designation shortens the review period from the standard ten months to six months from the filing acceptance of the BLA, and therefore, there is a PDUFA target action date of February 23, 2022.

The FDA will review the BLA for tebentafusp 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 granted Breakthrough Therapy Designation to tebentafusp for the treatment of HLA-A\*02:01-positive adult patients with unresectable or mUM. Over 150 patients have accessed tebentafusp through the global early access program across 14 countries.

In August, the European Medicines Agency (EMA)'s Committee for Medicinal Products for Human Use (CHMP), accepted the Company's MAA. In July, the EMA agreed to the Company's request for accelerated assessment of its MAA based on the determination that tebentafusp is a product of major interest for public health and therapeutic innovation. Accelerated assessment potentially reduces the time frame for the CHMP and Committee for Advanced Therapies to review the Company's submitted MAA for advanced therapies. While the CHMP review period of a MAA can take up to 210 days, the accelerated assessment reduces the timeframe for review of the MAA to 150 days (excluding clock-stops).

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

In the third 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, and ovarian. 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 the initial Phase 1 data at the ESMO IO Congress in December. Immunocore will also host an investor call on December 6<sup>th</sup> that will be accessible via the 'Investor Relations' section of the Company's website.

#### ***IMC-F106C targeting PRAME***

In the third 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 the initial Phase 1 data in mid-2022.

#### ***IMC-I109V targeting HBV***

In the third quarter, the Company continued to enroll patients in the IMC-I109V global Phase 1 single ascending dose trial. IMC-I109V is the first candidate in development using the Company'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.

#### ***IMC-M113V targeting HIV***

In the third quarter, the Company continued to advance IMC-M113V, an ImmTAV molecule target an HIV gag antigen bispecific TCR molecule. The Company's HIV programs are funded by the Bill & Melinda Gates Foundation, and regulatory submission to enable clinical testing is anticipated in the second half of 2021.

### **Financial Results**

Basic and diluted loss per share was £0.69 or \$0.93 for the three months ended September 30, 2021 compared to an adjusted £0.72 for the three months ended September 30, 2020. Basic and diluted loss per share was £2.19 or \$2.95 for the nine months ended September 30, 2021 compared to an adjusted £2.02 for the nine months ended September 30, 2020. Total operating loss for the three months ended September 30, 2021 was £31.0 million or \$41.7 million compared to £23.4 million for the same period last year. Total operating loss for the nine months ended September 30, 2021 was £97.3 million or \$131.1 million compared to £66.0 million for the same period in the prior year. The increases in operating loss were driven by increases in employee costs associated with a non-cash share-based payment charge.

Revenue for the three and nine months ended September 30, 2021 was £5.9 million or \$8.0 million and £19.9 million or \$26.8 million, respectively, as compared to £6.7 million and £22.7 million, respectively, for the three and nine months ended September 30, 2020. The decrease in revenue was primarily due to a reduction in activity under our collaboration agreements.

For the three and nine months ended September 30, 2021, our research and development ("R&D") expenses were £16.8 million or \$22.6 million and £53.2 million or \$71.6 million, respectively, as compared to £20.4 million and £57.6 million, respectively, for the three and nine months ended September 30, 2020. The reduction in R&D expenses was largely attributable to a reduction in clinical trial activity for tebentafusp as we seek regulatory approval and prepare for commercial launch.

For the three and nine months ended September 30, 2021, our administrative expenses were £20.0 million or \$27.0 million and £64.0 million or \$86.3 million, respectively, compared to £9.7 million and £31.6 million respectively, for the three and nine months ended September 30, 2020. The overall increase was driven by a £6.4 million and £19.3 million increase, respectively, in the non-cash share-based payment charge. In addition, pre-commercial expenditure relating to tebentafusp increased by £4.8 million and £10.4 million, respectively, in the three and nine months ended September 30, 2021.

Cash and cash equivalents were £256.6 million or approximately \$345.6 million as of September 30, 2021 compared to £129.7 million as of December 31, 2020.

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### **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 Priority Review; Real Time Oncology Review; Breakthrough Therapy Designation, Fast Track designation and orphan drug designation by the FDA in the United States; orphan drug status in the European Union; 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 in tebentafusp clinical trials for metastatic uveal melanoma, please visit [ClinicalTrials.gov](http://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 expected timing of a BLA review and action date for tebentafusp for the treatment of mUM, 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, IMC-I109V and IMC-M113V, 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.

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## Consolidated Statement of Loss

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

	Three Months Ended September 30,		
	2021	2020	
	\$'000	£'000	£'000
Revenue	7,980	5,924	6,652
Research and development expenses	(22,627)	(16,798)	(20,409)
Administrative expenses	(27,005)	(20,048)	(9,714)
Net other operating (loss) income	(38)	(28)	52
<b>Operating loss</b>	<b>(41,690)</b>	<b>(30,950)</b>	<b>(23,419)</b>
Finance income	11	8	367
Finance costs	(1,774)	(1,317)	(570)

<b>Non-operating expense</b>	<u>(1,763)</u>	<u>(1,309)</u>	<u>(203)</u>
<b>Loss before taxes</b>	<u>(43,453)</u>	<u>(32,259)</u>	<u>(23,622)</u>
Income tax credit	<u>2,862</u>	<u>2,125</u>	<u>4,265</u>
<b>Loss for the period</b>	<u><u>(40,591)</u></u>	<u><u>(30,134)</u></u>	<u><u>(19,357)</u></u>

**Comparison of the Nine Months Ended June 30, 2021 and 2020:**

	Nine Months Ended September 30,		
	2021		2020
	\$'000	£'000	£'000
Revenue	26,842	19,927	22,694
Research and development expenses	(71,598)	(53,154)	(57,566)
Administrative expenses	(86,252)	(64,033)	(31,569)
Net other operating (expense) / income	<u>(94)</u>	<u>(70)</u>	<u>408</u>
<b>Operating loss</b>	<u><b>(131,102)</b></u>	<u><b>(97,330)</b></u>	<u><b>(66,033)</b></u>
Finance income	57	42	1,972
Finance costs	<u>(6,014)</u>	<u>(4,465)</u>	<u>(2,272)</u>
<b>Non-operating expense</b>	<u><b>(5,957)</b></u>	<u><b>(4,423)</b></u>	<u><b>(300)</b></u>
<b>Loss before taxes</b>	<u><b>(137,059)</b></u>	<u><b>(101,753)</b></u>	<u><b>(66,333)</b></u>
Income tax credit	<u>12,957</u>	<u>9,619</u>	<u>11,120</u>
<b>Loss for the period</b>	<u><u><b>(124,102)</b></u></u>	<u><u><b>(92,134)</b></u></u>	<u><u><b>(55,213)</b></u></u>

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

	Nine Months Ended September 30,		
	2021	2021	2020
	\$'000	£'000	£'000
		(unaudited)	
Cash and cash equivalents at beginning of year	174,727	129,716	73,966
Net cash flows used in operating activities	(107,461)	(79,778)	(40,674)
Net cash flows used in investing activities	(137)	(102)	(670)
Net cash flows from financing activities	278,413	206,691	23,978
Net foreign exchange difference on cash held	<u>32</u>	<u>24</u>	<u>87</u>
Cash and cash equivalents at end of period	<u><u>345,574</u></u>	<u><u>256,551</u></u>	<u><u>56,687</u></u>

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

	September	December 31,
	30,	2020
	2021	2020
	£'000	£'000
<b>Non-current assets</b>		
Property, plant and equipment	10,043	13,754
Right of use assets	22,772	23,093
Investment in sub-lease	188	776
Other non-current financial assets	5,609	4,410
Deferred tax asset	<u>2,257</u>	<u>2,230</u>
<b>Total non-current assets</b>	<u><b>40,869</b></u>	<u><b>44,263</b></u>
<b>Current assets</b>		
Trade and other receivables	10,765	10,280
Tax receivable	22,555	12,935
Cash and cash equivalents	<u>256,551</u>	<u>129,716</u>
<b>Total current assets</b>	<u><b>289,871</b></u>	<u><b>152,931</b></u>
<b>Total assets</b>	<u><b>330,740</b></u>	<u><b>197,194</b></u>
<b>Equity</b>		
Share capital	88	64
Share premium	211,930	-
Foreign currency translation reserve	71	163
Other reserves	386,167	386,167
Share-based payment reserve	45,634	18,821
Accumulated deficit	<u>(442,003)</u>	<u>(349,869)</u>

<b>Total equity</b>	<b>201,887</b>	<b>55,346</b>
<b>Non-current liabilities</b>		
Interest-bearing loans and borrowings	37,280	36,654
Deferred revenue	10,681	24,868
Lease liabilities	25,486	25,190
Provisions	81	138
<b>Total non-current liabilities</b>	<b>73,528</b>	<b>86,850</b>
<b>Current liabilities</b>		
Interest-bearing loans and borrowings	546	—
Trade and other payables	28,815	25,728
Deferred revenue	24,450	27,118
Lease liabilities	1,369	2,043
Provisions	145	109
<b>Total current liabilities</b>	<b>55,325</b>	<b>54,998</b>
<b>Total liabilities</b>	<b>128,853</b>	<b>141,848</b>
<b>Total equity and liabilities</b>	<b>330,740</b>	<b>197,194</b>