



Immunocore presents promising initial Phase 1 data for first off-the-shelf TCR therapy targeting PRAME at the ESMO 2022 Congress

September 9, 2022

Immunocore presents promising initial Phase 1 data for first off-the-shelf TCR therapy targeting PRAME at the ESMO 2022 Congress

Data from Phase 1 dose escalation trial shows IMC-F106C, a PRAME×CD3 ImmTAC, activates T cells and is well tolerated

Durable RECIST responses and reduction in circulating tumor DNA (ctDNA) observed across multiple solid tumors

Four expansion arms enrolling in cutaneous melanoma, ovarian, lung, and endometrial cancers

Company to host a live webcast and conference call today at 12:30 PM EDT / 6:30 PM CEST

(OXFORDSHIRE, England & CONSHOHOCKEN, Penn. & ROCKVILLE, Md., US, 9 September 2022) [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, autoimmune and infectious diseases, has released today initial Phase 1 data for the first off-the-shelf ImmTAC[®] targeting PRAME, demonstrating that IMC-F106C is well tolerated and resulted in durable responses across multiple solid tumor types.

The initial data from the ongoing Phase 1 dose escalation trial of IMC-F106C is the subject of a presentation today at 4:40 PM CEST/10:40 AM EDT, in the Investigational Immunotherapy Proffered Paper session at the European Society for Medical Oncology (ESMO) Congress. The presentation can be accessed in the 'News & Events' section of the Investor Relations section of the [Company's website](#).

"The durable responses in heavily pre-treated patients show that our PRAME-targeted bispecific therapy, IMC-F106C, can deliver meaningful benefits to patients across a range of cancer types," said Bahija Jallal, Chief Executive Officer of Immunocore. "Based on this promising data, we have initiated expansion arms in multiple tumor types to further assess the efficacy."

Initial Phase 1 Clinical Data

As of 18 July 2022, 55 patients have been treated across 10 dose cohorts. IMC-F106C was well-tolerated, with treatment-related adverse events (AEs) that were manageable and consistent with the mechanism of action. The most frequent treatment-related AE reported was cytokine release syndrome (CRS), which was mostly Grade 1 (none were Grade ≥3) and occurred predominantly during the initial three doses. None of the related AEs led to treatment discontinuation or patient death.

Dr. Omid Hamid, Chief, Translational Research and Immunotherapy, Co-Director, Melanoma Therapeutics at Cedars-Sinai Cancer at the Angeles Clinic and Research Institute, said: "ImmTAC therapies are designed to provide potent and target-specific T-cell response, overcoming resistance in immune excluded tumors. Through redirection and activation of non-tumor-specific T cells, as shown in this trial with IMC-F106C, we can influence a diverse range of tumors leading to durable response. This trial shows tolerability and activity in a wide range of tumors, including checkpoint inhibitor pre-treated patients. I look forward to upcoming cohorts in combination with checkpoint inhibitors and chemotherapy."

Doses of ≥ 20 mcg were clinically active and had consistent and robust interferon gamma induction, a specific marker of T cell activation. Most of the patients in these active dose cohorts were enrolled without prospective PRAME testing. In these patients, PRAME expression was analyzed retrospectively; the vast majority were positive, and the average expression was high (median H score 188).

In the clinically active dose cohorts, durable partial responses (PR) were observed in 2/6 patients with cutaneous melanoma, 2/4 with ovarian cancer and 3/6 with tebentafusp-naïve uveal melanoma (UM) (0/5 response in patients with UM who had progressed on prior tebentafusp). All ovarian patients were platinum-resistant, and all cutaneous melanoma patients had progressed on prior anti-PD1 and anti-CTLA4. Six of the seven PRs are still ongoing, including two for over seven months. Ten additional efficacy evaluable patients across four other tumor types had a best RECIST response of stable disease or progressive disease. A majority of patients evaluable for circulating tumor DNA (ctDNA) had at least a 50% reduction.

Ongoing Expansion Arms in Four Cancer Types

The Company has initiated patient enrollment into four expansion arms in cutaneous melanoma, ovarian, non-small cell lung cancer (NSCLC), and endometrial cancers. The IMC-F106C-101 trial is adaptive and includes the option for Phase 2 expansion, allowing for approximately 100 patients treated per tumor type in the Phase 1 and 2 expansion arms. Dose escalation continues in additional solid tumors as well as plans for combination arms with standards-of-care.

About the Trial (IMC-F106C-101)

The Phase 1 dose escalation trial was designed to determine the maximum tolerated dose (MTD), as well as to evaluate the safety, preliminary anti-tumor activity and pharmacokinetics of IMC-F106C, a bispecific protein built on Immunocore's ImmTAC[®] technology, and the Company's first molecule to target the PRAME antigen.

Following pre-screening for the HLA-A*02:01 allele and, where required, for PRAME expression, patients were infused on a weekly dosing regimen, with intra-patient escalation during the initial three weeks. Tumor types with high PRAME prevalence were enrolled regardless of PRAME expression testing, which was evaluated retrospectively. Tumor types with lower PRAME prevalence required testing for PRAME expression prior to study entry. Patients were first scanned at nine weeks, and every nine weeks thereafter.

Conference Call Information

Immunocore will host a live webcast and conference call today beginning at 12:30 PM EDT to discuss the results with Dr. Omid Hamid, Chief, Translational Research and Immunotherapy, Co-Director, Melanoma Therapeutics at Cedars-Sinai Cancer at the Angeles Clinic and Research Institute. A live webcast of the conference call will be available under 'News & Events' in the Investor Relations section of Immunocore Holdings'

website at www.immunocore.com. The presentation from today's call and the archived webcast will be available on Immunocore's website after the conference call concludes and will be available for 30 days following the call.

##

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 clinical benefits of IMC-F106C for a wide range of cancers, including its ability to influence a diverse range of tumors and ability to result in a durable response; the timing of patient enrollment for and expansion arms of the IMC-F106C-101 trial, including the option for Phase 2 expansion; and expectations regarding the design, progress, timing, scope and results of Immunocore's existing and planned clinical trials, including the IMC-F106C-101 trial, including statements regarding upcoming cohorts, trial expansion and the timing of the availability of future clinical trial results. 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 and evolving COVID-19 pandemic on the Company's business, strategy, clinical trials and 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, including IMC-F106C, or commercial supply of KIMMTRAK or any future approved product, including as a result of the COVID-19 pandemic, war in Ukraine or global geopolitical tension; Immunocore's ability to obtain and maintain regulatory approvals for its product candidates, including KIMMTRAK and IMC-F106C; its ability to develop, manufacture and commercialize IMC-F106C and its other 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; the delay of the IMC-F106C-101 trial or any other 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; actions of regulatory agencies, which may affect the initiation, timing and progress of the IMC-F106C-101 trial and Immunocore's other 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; unexpected safety or efficacy data observed during preclinical studies or clinical trials, including the IMC-F106C-101 trial; clinical trial site activation or enrollment rates that are lower than expected; changes in expected or existing competition; 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.

CONTACT:

Immunocore

Sébastien Desprez, Head of Communications

T: +44 (0) 7458030732

E: sebastien.desprez@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

Investor Relations

Clayton Robertson, Head of Investor Relations

T: +1 (215) 384-4781

E: ir@immunocore.com