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Immunocore announces the presentation of initial data from the Phase 1 ImmTAV® trial for chronic Hepatitis B at the EASL International Liver Congress™

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PRESS RELEASE

Immunocore announces the presentation of initial data from the Phase 1 ImmTAV® trial for chronic Hepatitis B at the EASL International Liver Congress™

IMC-I109V, T cell receptor bispecific, targets an envelope antigen

Single Ascending Dose portion of Phase 1 study to evaluate safety, antiviral activity, and pharmacokinetics

In the initial cohort, HBsAg declines and ALT elevations indicated that a single, very low dose of IMC-I109V elicited on-target activity, consistent with mechanism of action and without any adverse events

(OXFORDSHIRE, England & CONSHOHOCKEN, Penn. & ROCKVILLE, Md., US, 25 June 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 that initial data from the first three patients in the first-in-human clinical trial of IMC-I109V was presented at the EASL International Liver Congress in London, UK.

IMC-I109V is a TCR bispecific designed to specifically eliminate HBV-infected hepatocytes expressing hepatitis B surface antigen (HBsAg) via T cell redirection. IMC-I109V is designed to overcome T cell dysfunction by recruiting non-exhausted T cells to eliminate hepatocytes harbouring covalently closed circular DNA or integrated HBV DNA. Elimination of these cells is necessary to achieve a state of 'functional cure' defined as sustained HBsAg loss in addition to undetectable HBV DNA 6 months post-treatment. Since the mechanism results in hepatocyte lysis, transient liver enzyme increases are expected, necessitating a conservative dosing schedule in the Company's first-in-human study of IMC-I109V.

In this first cohort, three patients each received a single dose of 0.8 mcg, based on the minimum anticipated biological effect level (MABEL). The dose in this initial cohort was well tolerated and was not associated with adverse events were reported in any patient. The maximum serum concentrations of IMC-I109V were consistent with the dose level. By hour 12, serum concentrations declined below the lower limit of quantification. IL-6 cytokine levels increased within the first 24 hours in all three patients, which is consistent with the IMC-I109V mechanism of action. Small and transient increases in alanine transaminase (ALT), albeit within the normal range, were observed in the first few days after dosing, before returning to normal levels. In two of the three patients, serum HBsAg levels transiently decreased, with the same kinetics as ALT, by 11-15% during Days 3-15 post infusion, before returning to baseline within 3 weeks post-infusion.

"We designed our T cell receptor based bispecific proteins to harness the immune system to potentially achieve a functional cure for HBV," **said David Berman, Head of Research & Development at Immunocore**. "Although only a few patients received a single, very low dose of IMC-I109V, we are very encouraged by our observations of transient decrease in HBV surface antigen, as well as transient elevations in ALT and cytokines, which match the profile we had hypothesized based on the IMC-I109V mechanism of action. We look forward to enrolling more patients at higher doses in the Phase 1 program."

The trial is an open label study evaluating the safety, antiviral activity, and pharmacokinetics of IMC-I109V in HLA-A*02:01 positive patients with chronic hepatitis B who are non-cirrhotic, HBeAg-negative and virally suppressed on nucleos(t)ide analogues. Part 1 is a single ascending dose to identify a safe and pharmacologically active dose. Part 2 is a multiple ascending dose to evaluate safety and anti-HBV activity of repeated doses over 24 weeks.

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About ImmTAV molecules and infectious diseases
ImmTAV (Immune mobilising monocolonal TCRs Against Virus) molecules are novel bispecific molecules that, like ImmTAC (Immune mobilising monoclonal TCRs Against Cancer) molecules, are designed to enable the immune system to recognize and eliminate virally infected cells.

Immunocore is advancing clinical candidates to cure patients with HIV and HBV. The Company aims to achieve a reduction in viral reservoirs to enable sustained control of HIV after stopping antiretroviral therapy (ART), without the risk of virological relapse or onward transmission. This is known as 'functional cure'. For the treatment of HBV, the Company aims to achieve sustained loss of circulating viral antigens and markers of viral replication after stopping medication for people living with chronic hepatitis B.

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 therapeutic potential of IMC-I109V to be an effective treatment for patients with HBV; the expected clinical benefits of IMC-I109V including its potential as a “functional cure”; anticipated results from the Phase 2 portion of the clinical trial of IMC-I109V and expectations regarding the ability to recruit and enroll additional patients in the clinical trial of IMC-I109V. 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; its ability to execute its commercialization strategy for KIMMTRAK including the timing or likelihood of expansion into additional markets or geographies; 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 in the United States, European Union and other territories; that positive results from earlier pre-clinical studies of Immunocore’s product candidates may not necessarily be predictive of the results from required later pre-clinical studies and future clinical trials; 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; 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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