

Immunocore announces dosing of first patient with ImmTAV® bispecific for HIV

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PRESS RELEASE

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IMC-M113V, T cell receptor bispecific, targets an HIV Gag antigen

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

(OXFORDSHIRE, England & CONSHOHOCKEN, Penn. & ROCKVILLE, Md., US, 11 July 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 announces the dosing of the first patient in the first-in-human Phase 1 clinical trial of IMC-M113V, a new class of bispecific protein immunotherapy that is being developed for the treatment of patients with human immunodeficiency virus (HIV) infection.

IMC-M113V is the second candidate in development using Immunocore’s immune -mobilising monoclonal T cell receptors against virus (ImmTAV®) platform to enter clinical trials. IMC-M113V is an immunotherapeutic approach designed to specifically eliminate CD4+ cells that are persistently infected with HIV (‘reservoirs’). IMC-M113V targets a peptide derived from the Gag protein that is presented by HLA*A02 on the surface of HIV infected cells. Reduction in the number of these cells is one way to potentially achieve a state of viral suppression in the absence of anti-retroviral medications, or a ‘functional cure.’

There are currently over 30 antiretroviral medications spanning six drug classes approved for the treatment of HIV. If started early, antiretroviral therapy (ART) provides people with HIV with a normal life expectancy, prevents immunodeficiency and stops the spread of the virus. However, this treatment does not ‘cure’ the disease and must be continued for life to prevent relapse.

“HIV remains a major global public health challenge with the need for a functional cure” said **Lucy Dorrell MD, Head of Infectious Diseases at Immunocore**. “IMC-M113V is the first soluble TCR bispecific targeting HIV to enter the clinic. We hope that the start of this study is the next step to potentially bring a transformative treatment to millions of HIV infected people around the world.”

As part of the collaboration agreement between Immunocore and the Bill and Melinda Gates Foundation, Immunocore and the Gates Foundation are committed to working together for HIV product candidate development and ensuring that any resulting HIV product that receives necessary regulatory approval is made available to people in developing countries at an affordable price.

Professor Sarah Fidler, PhD, Imperial College of London Department of Infectious Disease commented: “There are nearly 38 million people around the world living with HIV and despite the accessibility of anti-retroviral therapy (ART), this is still a significant unmet need. The potential for a TCR therapy for HIV would be a ground-breaking development which would remove the need for patients to continuously take ART- for the remainder of their lives, providing significant relief to one of the world’s largest public health issues.”

The trial is an ongoing open label study evaluating the safety, antiviral activity, and pharmacokinetics of IMC-M113V in HLA-A*02:01 positive patients with HIV who are currently receiving standard of care anti-retroviral therapy.

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About ImmTAV molecules and infectious diseases

ImmTAV (Immune mobilising monoclonal 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 hepatitis B virus (HBV). The Company aims to achieve sustained control of HIV after patients stop 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 HBV.

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 success of Company’s collaboration with the Gates Foundation; statements regarding clinical data from the ongoing trial of IMC-M113V; the ability of IMC-M113V to be an effective or transformative treatment for patients with HIV infection; the expected clinical benefits of IMC-M113V including its potential as a “functional cure”; and the Company’s plan for future development of IMC-M113V.

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; results from earlier pre-clinical studies of Immunocore's product candidates including IMC-M113V 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 of IMC-M113V or future regulatory approval; Immunocore's ability to obtain, maintain and enforce intellectual property protection; unexpected safety or efficacy data observed during preclinical studies or clinical trials; clinical trial site activation or enrolment 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 including its collaboration with the Gates Foundation. 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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