Immunocore announces upcoming presentation and posters at ASCO 2024

(OXFORDSHIRE, England & CONSHOHOCKEN, Penn. & ROCKVILLE, Md., US, 24 April 2024) Immunocore Holdings plc (Nasdaq: IMCR) (“Immunocore” or the “Company”) a commercial-stage biotechnology company pioneering and delivering transformative immunomodulating medicines to radically improve outcomes for patients with cancer, infectious diseases and autoimmune diseases, will present Phase 1 expansion data for brenetafusp (IMC-F106C), the first off-the-shelf ImmTAC therapy targeting PRAME, in patients with late-line cutaneous melanoma, all previously treated with anti-PD1 and the vast majority having received ipilimumab, at the 2024 American Society of Oncology (ASCO) Annual Meeting commencing on 31 May.

The Company will also present four posters, including one trial-in-progress poster of the Phase 3 PRISM-MEL301 trial with brenetafusp in combination with nivolumab versus standard nivolumab regimens in HLA-A*02:01+ patients with first-line advanced melanoma, and three posters sharing clinical and translational data about KIMMTRAK in metastatic uveal melanoma.

Presentation and poster details

Title: Phase 1 safety and efficacy of IMC-F106C, a PRAME×CD3 ImmTAC bispecific, in post-checkpoint cutaneous melanoma
Presenting author: Omid Hamid
Session: Oral Abstract Session – Melanoma/Skin Cancers, Friday 31 May 2024; 2:45-5:45 p.m. CT / 1:45-4:45 p.m. ET

Title: A Phase 3 trial of IMC-F106C (PRAME × CD3) plus nivolumab versus standard nivolumab regimens in HLA-A*02:01+ patients with previously untreated advanced melanoma (PRISM-MEL-301)
Presenting author: Georgina Long
Session: Poster Session – Melanoma/Skin Cancers, Saturday 1 June 2024, 1:30-4:30 p.m. CT / 12:30-3:30 p.m. ET

Title: Stable disease with confirmed tumor reduction has a similar clinical outcome as RECIST partial response for tebentafusp in metastatic uveal melanoma
Presenting author: Alexandra Ikeguchi
Session: Poster Session – Melanoma/Skin Cancers, Saturday 1 June 2024, 1:30-4:30 p.m. CT / 12:30-3:30 p.m. ET
Title: Association between clinical and disease characteristics and detectable or undetectable baseline ctDNA in patients with metastatic uveal melanoma
Presenting author: Paul Nathan
Session: Poster Session – Melanoma/Skin Cancers, Saturday 1 June 2024, 1:30-4:30 p.m. CT / 12:30-3:30 p.m. ET

Title: Baseline and serial ctDNA dynamics predicts outcomes in patients treated with first-line tebentafusp including those who were and were not treated beyond progression
Presenting author: Ryan Sullivan
Session: Poster Session – Melanoma/Skin Cancers, Saturday 1 June 2024, 1:30-4:30 p.m. CT / 12:30-3:30 p.m. ET

Conference Call
Immunocore will host an investor and analyst event and webcasted conference call on Friday 31 May 2024 at 6:15 p.m. CT with Dr. Diwakar Davar. The webcast will be available under ‘News & Events’ in the Investor Relations section of Immunocore Holdings’ website at www.immunocore.com.

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About ImmTAC® molecules for cancer

Immunocore’s proprietary T cell receptor (TCR) technology generates a novel class of bispecific biologics called ImmTAC (Immune mobilizing monoclonal TCRs Against Cancer) molecules that are designed to redirect the immune system to recognize and kill cancerous cells. ImmTAC molecules are soluble TCRs engineered to recognize intracellular cancer antigens with ultra-high affinity and selectively kill these cancer cells via an anti-CD3 immune-activating effector function. Based on the demonstrated mechanism of T cell infiltration into human tumors, the ImmTAC mechanism of action holds the potential to treat hematologic and solid tumors, regardless of mutational burden or immune infiltration, including immune “cold” low mutation rate tumors.

About KIMMTRAK

KIMMTRAK is a novel bispecific protein comprised of a soluble T cell receptor fused to an anti-CD3 immune-effector function. KIMMTRAK specifically targets gp100, a lineage antigen expressed in melanocytes and melanoma. This is the first molecule developed using Immunocore’s ImmTAC technology platform designed to redirect and activate T cells to recognize and kill tumor cells. KIMMTRAK has been approved for the treatment of HLA-A*02:01-positive adult patients with unresectable or metastatic uveal melanoma in the United States, European Union, Canada, Australia, and the United Kingdom.

About PRISM-MEL301 – Phase 3 trial with brenetafusp (IMC-F106C, PRAMExCD3) in 1L advanced cutaneous melanoma

The Phase 3 registrational trial will randomize patients with previously untreated, HLA-A*02:01-positive, advanced melanoma to IMC-F106C + nivolumab versus nivolumab or nivolumab + relatlimab, depending on the country where the patient is enrolled. The study will initially randomize to three arms: two IMC-F106C dose regimens (40 mcg and 160 mcg) and control arm and will discontinue one of the IMC-F106C dose regimens after an initial...
review of the first 60 patients randomized to the two experimental arms (90 patients randomized total). The primary endpoint of the trial is progression free survival (PFS) by blinded independent central review (BICR), with secondary endpoints of overall survival (OS) and overall response rate (ORR).

About the IMC-F106C-101 Phase 1/2 trial

IMC-F106C-101 is a first-in-human, Phase 1/2 dose escalation trial in patients with multiple solid tumor cancers including non-small cell lung cancer (NSCLC), small-cell lung cancer (SCLC), endometrial, ovarian, cutaneous melanoma, and breast cancers. 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 brenetafusp (IMC-F106C), a bispecific protein built on Immunocore’s ImmTAC technology, and the Company’s first molecule to target the PRAME antigen. The Company has initiated patient enrollment into four expansion arms in cutaneous melanoma, ovarian, NSCLC, and endometrial carcinomas. 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, including checkpoint inhibitors, chemotherapy, and tebentafusp.

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. The Company’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 in the United States, European Union, Canada, Australia, and the United Kingdom.

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,” “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 expected clinical benefits of KIMMTRAK, brenetafusp and the Company’s other product candidates, including progression free survival and extended overall survival benefit; expectations regarding receipt of regulatory approvals and completion of related procedures; the value proposition of Immunocore’s products and product candidates, including KIMMTRAK and brenetafusp; future development plans of Immunocore’s products and product candidates, including KIMMTRAK and brenetafusp; expectations regarding the design, progress, timing, scope and results of
Immunocore’s existing and planned clinical trials, including the Phase 3 PRISM-MEL301 trial with brenetafusp plus nivolumab versus standard nivolumab in 1L advanced cutaneous melanoma and the Phase 1/2 dose escalation trial with brenetafusp in patients with multiple solid tumor cancers including non-small cell lung cancer (NSCLC), small-cell lung cancer (SCLC), endometrial, ovarian, cutaneous melanoma, and breast cancers. Any forward-looking statements are based on management’s current expectations and beliefs of future events and are subject to a number of risks and uncertainties that could cause actual events or 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 worsening macroeconomic conditions on the Company’s business, 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 or commercial supply of KIMMTRAK or any future approved products, including as a result of health epidemics or pandemics, war in Ukraine, the conflict between Hamas and Israel, or global geopolitical tension; Immunocore’s ability to obtain and maintain regulatory approval of its product candidates, including KIMMTRAK; 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; Immunocore’s ability to successfully expand the approved indications for KIMMTRAK or obtain marketing approval for KIMMTRAK in additional geographies in the future; the delay of any current or planned clinical trials, whether due to 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; competition with respect to market opportunities; unexpected safety or efficacy data observed during preclinical studies or clinical trials; actions of regulatory agencies, which may affect the initiation, timing and progress of 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 the worsening macroeconomic conditions, including inflation, interest rates and unfavorable general market conditions, and the impacts thereon of the war in Ukraine, the conflict between Hamas and Israel, and global geopolitical tension; Immunocore’s ability to obtain, maintain and enforce intellectual property protection for KIMMTRAK or any of its product candidates it or its collaborators are developing; 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 10-K for the year ended December 31, 2023 filed with the Securities and Exchange Commission on February 28, 2024, 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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Source: Immunocore Holdings plc