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IMC-F106C is Immunocore’s first-in-class bispecific TCR ImmTAC candidate targeting PRAME HLA-A02; nivolumab is manufactured by Bristol Myers Squibb

The clinical trial collaboration relates to Immunocore’s PRISM-MEL-301 registrational Phase 3 clinical trial in first-line advanced cutaneous melanoma, evaluating IMC-F106C in combination with nivolumab versus a control arm of either nivolumab or the fixed-dose combination of nivolumab and relatlimab

(OXFORDSHIRE, England & CONSHOHOCKEN, Penn. & ROCKVILLE, Md., US, 22 February 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, today announced that it has entered into a clinical trial collaboration and supply agreement with Bristol Myers Squibb (NYSE:BMY) to investigate Immunocore’s ImmTAC bispecific TCR (T cell receptor) candidate targeting PRAME HLA-A02, IMC-F106C, in combination with Bristol Myers Squibb’s nivolumab, in first-line advanced cutaneous melanoma.

Under the terms of the collaboration, Immunocore will sponsor and fund the registrational Phase 3 clinical trial of IMC-F106C in combination with nivolumab in first-line advanced cutaneous melanoma (PRISM-MEL-301), and Bristol Myers Squibb will provide nivolumab.

The PRISM-MEL-301 trial will randomize HLA-A^02:01+ first-line advanced cutaneous melanoma patients to IMC-F106C + nivolumab versus a control arm of either nivolumab or the fixed-dose combination of nivolumab and relatlimab, depending on the country where the patient is enrolled. Immunocore plans to randomize the first patient in this trial in the first quarter of 2024.

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About PRISM-MEL301 – Phase 3 trial with IMC-F106C (PRAME HLA-A02) in 1L advanced cutaneous melanoma

The Phase 3 registrational trial (NCT06112314) will randomize patients with previously untreated, HLA-A*02:01 positive, advanced melanoma to IMC-F106C + nivolumab versus nivolumab or the fixed-dose combination of nivolumab and relatlimab, depending on the country where the patient is enrolled. The trial 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 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), as well as safety.

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 benefits of Immunocore’s collaboration with Bristol Meyers Squibb; the risk that the Company may not realize the anticipated benefits of its collaboration with Bristol-Meyers Squibb; and expectations regarding the design, progress, timing, enrollment, randomization, scope, expansion, funding, and results of the PRISM-MEL301 registrational Phase 3 clinical trial of IMC-F106C (PRAME- HLA-A02) in combination with nivolumab in first-line cutaneous melanoma (PRISM-MEL-301). 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 Immunocore’s control. These risks and uncertainties include, but are not limited to, the impact of worsening macroeconomic conditions on Immunocore’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; the timing and sufficiency of clinical trial outcomes to support potential approval of any of Immunocore’s product candidates or those of, or combined with, its collaboration partners such as IMC-F106C (PRAME-HLA A02); Immunocore’s ability to obtain and maintain regulatory approval of its products and 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 worsening macroeconomic conditions, including changes in inflation and 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, including the risk that Immunocore may not realize the anticipated benefits of its collaboration with Bristol Myers Squibb. 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, 2022 filed with the Securities and Exchange Commission on March 1, 2023, as well as discussions of potential risks, uncertainties, and other important factors in Immunocore’s subsequent filings with the Securities and Exchange Commission. All information in this press release is as of the date of the release, and Immunocore undertakes no duty to update this information, except as required by law.

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