

## Immunocore and Gadeta Announce Agreement to Develop First Gamma Delta ( $\gamma\delta$ ) TCR ImmTAC for Solid Tumors

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*Gamma delta TCRs offer potential to address large number of patients without HLA restrictions*

*Agreement combines Gadeta's gamma delta target and TCR identification expertise with Immunocore's TCR bispecific engineering, development and commercialization capabilities to develop gamma delta ImmTAC therapies*

*Immunocore has an option for an exclusive license to further research, develop and commercialize ImmTAC candidates from the collaboration*

(OXFORDSHIRE, England & CONSHOHOCKEN, Penn. & ROCKVILLE, Md., US, UTRECHT, Netherlands & BOSTON, Mass. US, 02 December 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, and Gadeta B.V., an innovative clinical-stage biopharmaceutical company pioneering the development of gamma delta ( $\gamma\delta$ ) TCR-based immunotherapies for solid tumors, announced today that they will collaborate on the first  $\gamma\delta$  ImmTAC<sup>®</sup> for solid tumors, including colorectal cancer.

"Immunocore pioneered TCR therapy with the launch of KIMMTRAK and we continue to push the edge of TCR science, including researching non-HLA restricted TCR therapies, both internally and through collaborations that complement our platform," said David Berman, Head of Research and Development of Immunocore. "We are very pleased to collaborate with Gadeta to combine their expertise in gamma delta TCRs with our scientific, development, and commercialization capabilities to deliver new TCR therapies."

"Gadeta is excited to work with Immunocore on bringing these novel, soluble  $\gamma\delta$ -TCRs to patients with solid tumors," said Marcel Zwaal, Chief Executive Officer of Gadeta. "This agreement shows the potential of Gadeta's new tumor targeting mechanism and it provides us with an opportunity for maximizing the impact of our suite of technologies for T cell related therapies, including the NOVA  $\gamma\delta$ -TCR discovery platform."

Gamma delta T cells are an important subset of immune cells that sit on the boundary of the innate and adaptive immune systems. They patrol the body using their T cell receptors to scan for cellular alarm signals, some of which are not HLA restricted, such as modified cell surface proteins or protein clusters caused by cancer or pathogens. Gadeta has identified a portfolio of novel, first-in-class,  $\gamma\delta$ -TCRs. One of those, referred to as '201, specifically recognizes a non-HLA restricted alarm signal on the surface of cancer cells. Gadeta is developing '201 TCR in its proprietary TEG (T Cells Engineered to Express a Defined Gamma Delta TCR) cell therapy platform as GDT201. Pre-clinical data for GDT201 show promising results across a wide range of colorectal cancer cell lines and the product will be evaluated in a Phase 1 trial for a range of solid tumor indications, slated to start in H2 2023. GDT201 remains fully owned by Gadeta.

Under the terms of the agreement, Immunocore and Gadeta will collaborate on '201  $\gamma\delta$ -TCR target discovery, and Immunocore will have the option to develop ImmTAC therapies derived from the '201 TCR as part of the research collaboration. Immunocore has an option for an exclusive license to further research, develop and commercialize an ImmTAC candidate from the collaboration. Gadeta is eligible to receive upfront, near-term option fee and research milestone payments. If Immunocore exercises its option for an exclusive license, Gadeta is eligible to receive development milestone and commercial milestone payments and is also entitled to receive royalties on sales of the product.

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#### 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.

#### About Gadeta

Gadeta is discovering novel gamma delta ( $\gamma\delta$ ) TCRs that enable the development of first-in-class cell therapies for the treatment of solid cancers. By harnessing  $\gamma\delta$ -TCRs, that naturally target stress related antigens expressed by cancer tissues, Gadeta's technology has the potential to deliver highly effective and novel therapy options to cancer patients. Gadeta's products target a wide array of cancer indications and in particular solid tumors, where cell therapies have not yet fulfilled the potential demonstrated in liquid cancers. For more information please visit: [www.gadeta.nl](http://www.gadeta.nl).

#### About KIMMTRAK<sup>®</sup>

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 Phase 3 IMCgp100-202 Trial

IMCgp100-202 (NCT03070392) is a randomized pivotal trial that evaluated overall survival (OS) of KIMMTRAK compared to investigator's choice

(either pembrolizumab, ipilimumab, or dacarbazine) in HLA-A\*02:01-positive adult patients with previously untreated mUM. KIMMTRAK demonstrated an unprecedented OS benefit with a Hazard Ratio (HR) in the intent-to-treat population favoring KIMMTRAK, HR=0.51 (95% CI: 0.37, 0.71);  $p < 0.0001$ , over investigator's choice (82% pembrolizumab; 13% ipilimumab; 6% dacarbazine).

## **IMPORTANT SAFETY INFORMATION**

Cytokine Release Syndrome (CRS), which may be serious or life-threatening, occurred in patients receiving KIMMTRAK. Monitor for at least 16 hours following first three infusions and then as clinically indicated. Manifestations of CRS may include fever, hypotension, hypoxia, chills, nausea, vomiting, rash, elevated transaminases, fatigue, and headache. CRS occurred in 89% of patients who received KIMMTRAK with 0.8% being grade 3 or 4. Ensure immediate access to medications and resuscitative equipment to manage CRS. Ensure patients are euvolemic prior to initiating the infusions. Closely monitor patients for signs or symptoms of CRS following infusions of KIMMTRAK. Monitor fluid status, vital signs, and oxygenation level and provide appropriate therapy. Withhold or discontinue KIMMTRAK depending on persistence and severity of CRS.

### **Skin Reactions**

Skin reactions, including rash, pruritus, and cutaneous edema occurred in 91% of patients treated with KIMMTRAK. Monitor patients for skin reactions. If skin reactions occur, treat with antihistamine and topical or systemic steroids based on persistence and severity of symptoms. Withhold or permanently discontinue KIMMTRAK depending on the severity of skin reactions.

### **Elevated Liver Enzymes**

Elevations in liver enzymes occurred in 65% of patients treated with KIMMTRAK. Monitor alanine aminotransferase (ALT), aspartate aminotransferase (AST), and total blood bilirubin prior to the start of and during treatment with KIMMTRAK. Withhold KIMMTRAK according to severity.

### **Embryo-Fetal Toxicity**

KIMMTRAK may cause fetal harm. Advise pregnant patients of potential risk to the fetus and patients of reproductive potential to use effective contraception during treatment with KIMMTRAK and 1 week after the last dose.

The most common adverse reactions ( $\geq 30\%$ ) in patients who received KIMMTRAK were cytokine release syndrome, rash, pyrexia, pruritus, fatigue, nausea, chills, abdominal pain, edema, hypotension, dry skin, headache, and vomiting. The most common ( $\geq 50\%$ ) laboratory abnormalities were decreased lymphocyte count, increased creatinine, increased glucose, increased AST, increased ALT, decreased hemoglobin, and decreased phosphate.

For more information, please see full Summary of Product Characteristics (SmPC) or full U.S. Prescribing Information (including BOXED WARNING for CRS).

### **About KIMMTRAKConnect**

Immunocore is committed to helping patients who need KIMMTRAK obtain access via our KIMMTRAKConnect program. The program provides services with dedicated nurse case managers who provide personalized support, including educational resources, financial assistance, and site of care coordination. To learn more, visit [KIMMTRAKConnect.com](https://www.kimmtrakconnect.com) or call 844-775-2273.

### **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 our product candidates and  $\gamma\delta$ -TCRs, including GDT201; expectations regarding the design, progress, timing, scope and results of Immunocore's existing and planned clinical trials and the Phase 1 trial for GDT201; and expectations regarding the success, outcome and terms of our and Gadeta's ability to perform our respective obligations under, our collaboration with Gadeta. 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 worsening macroeconomic conditions and the ongoing and evolving COVID-19 pandemic on Immunocore's or Gadeta's business, strategy, clinical trials, financial position 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 any approved product, including as a result of supply chain disruptions; Immunocore's ability to obtain and maintain regulatory approvals for its product candidates; Immunocore's ability to develop, manufacture and commercialize its product candidates; Immunocore's ability and plans in continuing to establish and expand a commercial infrastructure and to successfully market and sell KIMMTRAK and any future approved products; the delay of any 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 Immunocore's 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 such as rising inflation and interest rates, volatility in the capital markets and related market uncertainty, the COVID-19 pandemic, the 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; 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](mailto: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](mailto:immunocore@consilium-comms.com)

**Investor Relations**

Clayton Robertson, Head of Investor Relations

T: +1 (215) 384-4781

E: [clayton.robertson@immunocore.com](mailto:clayton.robertson@immunocore.com)

**Gadeta****Optimum Strategic Communications**

Mary Clark, Manel Mateus, Eleanor Cooper

T: +44 20 3922 0891

E: [gadeta@optimumcomms.com](mailto:gadeta@optimumcomms.com)