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targeting T cell receptors

PRESS RELEASE – IMMUNOCORE LIMITED

Immunocore's IMCgp100 Accepted for Adaptive Pathway Pilot Programme

Potential for Accelerated Regulatory Approval in Europe

(Oxford, UK, 9 September 2015) Immunocore Limited, a world-leading biotechnology company developing novel T cell receptor (TCR) based biological drugs to treat cancer, viral infections and autoimmune disease, today announced that its lead product, IMCgp100, has been accepted to participate in the European Medicines Agency's (EMA) Adaptive Pathways (formerly Adaptive Licensing) pilot programme. This is part of the EMA's strategy of providing timely access for patients to new medicines to treat serious conditions with a high unmet medical need.

Immunocore is one of a small number of companies to have been accepted into this programme and plans to seek conditional approval for IMCgp100 for the treatment of patients with metastatic uveal melanoma, a rare and fatal disease with few available treatment options.

Conversion to full approval will be subject to the successful completion of a Phase II clinical trial in uveal melanoma with long-term follow-up data.

Dr. Christina Coughlin, Chief Medical Officer at Immunocore, said: "We are delighted to have been accepted into the EMA Adaptive Pathways pilot programme, an accelerated development project that further underscores the potential benefits that IMCgp100 can bring to patients with uveal melanoma, a fatal disease that has few other treatment options. We are grateful for the collaborative regulatory feedback from the EMA on the design of our development programme as well as feedback from the European HTA agencies and patient advocacy organisations that are participating in our Adaptive Pathways pilot project." Dr. Coughlin added: "We are very pleased to be working with leading European experts in the clinical management of patients with uveal melanoma."

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Notes for editors

About Immunocore

Immunocore is one of the world's leading biotechnology companies, with a highly innovative immuno-oncology platform technology called ImmTACs. ImmTACs are a novel class of biologic drugs based on the Company's proprietary T cell receptor (TCR) technology which have the potential to treat diseases with high unmet medical need including cancer, viral infections and autoimmune diseases. Immunocore, based on decades of world-leading scientific innovation in the discovery of HLA targets and T cell receptor technology, has a pipeline of wholly-owned and partnered ImmTAC programmes with robust clinical data, validated by collaborations with world-leading pharmaceutical companies. Immunocore aims to leverage the utility of its platform across a wide range of indications to become a Premier Biotech company and world-leader in its field.

Immunocore's world-leading science and strong IP position has attracted major pharmaceutical companies including Genentech, GlaxoSmithKline, MedImmune, the biologics division of AstraZeneca, via discovery collaborations, as well as a co-discovery and co-development partnership with Lilly. The Company has also entered into combination trial collaborations with its lead programme, IMCgp100 in melanoma, with Medimmune and Lilly. Founded in 2008 originally out of Oxford University and headquartered outside Oxford, Immunocore now has more than 160 staff. Immunocore's current investors are well-renowned, leading international institutions including Woodford Investment Management, Malin Corporation, Eli Lilly and Company, RTW Investments, Fidelity Management & Research Company as well as other private shareholders. For more information, please visit <u>www.immunocore.com</u>

About EMA's Adaptive Pathways Pilot Programme

In establishing the Adaptive Pathways pilot programme, the EMA stated the following:

"The concept of Adaptive Pathways foresees either an initial approval in a welldefined patient subgroup with a high medical need and subsequent widening of the indication to a larger patient population, or an early regulatory approval (e.g. conditional approval), which is prospectively planned, and where uncertainty is reduced through the collection of post-approval data on the medicine's use in patients. This approach is particularly relevant for medicines with the potential to treat serious conditions with an unmet medical need and may reduce the time to a medicine's approval or to its reimbursement for targeted patient groups. It involves balancing the importance of timely patient access with the need for adequate, evolving information on a medicine's benefits and risks. The Adaptive Pathways approach builds on regulatory processes already in place within the existing European Union legal framework."

The pilot was initiated in March 2014 and was called "Adaptive Licensing" at the time. EMA changed the name to Adaptive Pathways "to better reflect the idea of a life-span approach to bring new medicines to patients with clinical drug development,

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licensing, reimbursement, and utilization in clinical practice, and monitoring viewed as a continuum."

About ImmTACs

Immunocore's proprietary technology is focused on small protein molecules called ImmTACs (Immune mobilising mTCR Against Cancer) that enable the immune system to recognise and kill cancerous or bacterially/virally infected cells.

Immunocore's ImmTACs, a new class of drug with ultra-high affinity for intracellular cancer targets, are synthetic, soluble T cell receptors (TCRs) that recognise diseased cells containing disease specific targets. The ImmTACs enable circulating T-cells to selectively identify and kill diseased cells. The ImmTAC platform is unique in its high specificity and potency and broad applicability to a wide range of intracellular targets and disease indications. ImmTACs can access up to nine-fold more targets than typical antibody-based therapies, including monoclonal antibodies.

TCRs naturally recognise diseased cells and Immunocore's world-leading competitive advantage is its ability to engineer high affinity TCRs and link them to an antibody fragment that activates a highly potent and specific T cell response to recognise and destroy cancer cells. The most advanced ImmTAC, IMCgp100, is currently in Phase IIa clinical trials for the treatment of late stage melanoma. Immunocore has a growing internal pipeline of ImmTACs addressing many different cancer types and has developed a broad database of intracellular cancer targets.

ImmTACs can address a significantly larger range of disease indications than currently respond to existing immuno-oncology agents and combine the characteristics of very high potency, encouraging safety and low cost of goods.