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Lilly and Immunocore Announce Immunotherapy-based Clinical Trial Collaboration in Melanoma

INDIANAPOLIS and OXFORD, England, June 29, 2015 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) and Immunocore Limited today announced that they have entered into an immunotherapy-based clinical trial collaboration to explore the utility of Immunocore's lead T cell receptor-based investigational therapeutic, IMCgp100, in combination with Lilly's galunisertib (LY2157299) and merestinib (LY2801653) for the treatment of melanoma. The goal of the collaboration is to identify combination regimens that provide synergies in efficacy and durability in patients with metastatic cutaneous and uveal melanomas.

Under the terms of the agreement, Immunocore and Lilly will conduct a Phase Ib/II clinical study evaluating the safety and preliminary efficacy of IMCgp100 in combination with galunisertib in metastatic cutaneous melanoma. A second Phase Ib/II study will be conducted combining IMCgp100 with merestinib in metastatic uveal melanoma. Lilly will act as trial sponsor. These studies are anticipated to begin in 2016. No financial terms were disclosed.

IMCgp100 and galunisertib are members of a new class of cancer treatments known as immunotherapies, which are designed to enhance the body's own immune system in fighting cancer and whose mechanisms of action have the potential to be complementary. IMCgp100 is Immunocore's most advanced Immune mobilizing mTCR Against Cancer molecules (ImmTAC), which are a novel class of bi-specific biologic drugs based on T cell receptors (TCRs) with ultra-high affinity for intracellular and extracellular cancer targets. Lilly's galunisertib is a small molecule inhibitor of TGF beta R1 kinase that in vitro selectively blocks TGF beta signaling. TGF beta promotes tumor growth, suppresses the immune system and increases the ability of tumors to spread in the body. Merestinib is Lilly's small molecule multi-kinase inhibitor that in vitro selectively blocks signaling of MET, MST1R (RON), AXL, and MKNK1/2, pathways that potentially play a role in metastatic uveal melanoma.

"This collaboration with Immunocore underscores Lilly's commitment to discovering the potential of combination therapies, which will be key to the future of cancer care for people fighting diseases such as melanoma," said Richard Gaynor, M.D., senior vice president, product development and medical affairs for Lilly Oncology. "Lilly is building a robust portfolio of potential advances in immunotherapy through our own research as well as with strategic collaborations like Immunocore."

Immunocore and Lilly entered into a co-discovery and co-development collaboration, announced in July 2014, to research and potentially develop other novel T cell-based cancer therapies built on Immunocore's ImmTAC platform.

"We are very pleased to be able to announce a second collaboration with Lilly after entering into a collaboration last year," said Eliot Forster, chief executive officer of Immunocore. "Combining our ImmTAC, IMCgp100 with Lilly's galunisertib and merestinib has the potential to transform the treatment of metastatic cutaneous and uveal melanoma. Immunocore is committed to the development of IMCgp100 in metastatic uveal and cutaneous melanoma where there is such great unmet medical need."

Immunocore recently announced clinical efficacy data in a Phase I/IIa trial with IMCgp100 in patients with advanced melanoma, as well as in the expansion cohort with uveal melanoma.

About Melanoma

Melanoma is a cancer that begins in the melanocytes. Other names for this cancer include *malignant melanoma* and *cutaneous melanoma*. Most melanoma cells still make melanin, so melanoma tumors are usually brown or black. But some melanomas do not make melanin and can appear pink, tan, or even white.

Melanomas can develop anywhere on the skin, but they are more likely to start on the trunk (chest and back) in men and on the legs in women. The neck and face are other common sites.

Melanoma is much less common than basal cell and squamous cell skin cancers, but it is far more dangerous. Like basal cell and squamous cell cancers, melanoma is almost always curable in its early stages. But it is much more likely than basal or squamous cell cancer to spread to other parts of the body if not caught early.[i]

According to the American Cancer Society's estimates for melanoma in the United States for 2015, about 73,870 new melanomas will be diagnosed (about 42,670 in men and 31,200 in women); and about 9,940 people are expected to die of

melanoma (about 6,640 men and 3,300 women).[ii]

Uveal (or ocular) melanoma is a cancer of the eye diagnosed in approximately 2,000-2,500 adults annually in the United States. In both the U.S. and Europe, this equates to about 5-7.5 cases per million people per year and, for people over 50 years old, the incidence rate increases to around 21 per million per year.[iii]

About IMCgp100 and ImmTACs

Immunocore's proprietary technology is focused on small protein molecules called ImmTACs (Immune mobilizing mTCR Against Cancer) that enable the immune system to recognize and kill cancerous 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 recognize diseased cells containing disease specific targets. The ImmTACs enable circulating T cells to selectively identify and kill diseased cells. The ImmTAC platform is unique and has very high specificity and potency as well as broad applicability to a wide range of intracellular targets. ImmTACs can access up to nine-fold more targets than typical antibody-based therapies, including monoclonal antibodies.

TCRs naturally recognize 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 recognize and destroy cancer cells.

The most advanced ImmTAC, IMCgp100, is currently in Phase IIa clinical trials for the treatment of late stage melanoma. Following completion of a Phase I study at the end of 2013, Immunocore initiated a Phase IIa study to optimize the dosing regimen of IMCgp100. Immunocore has a growing internal pipeline of ImmTACs addressing many different cancer types and has developed a broad database of intracellular cancer targets.

About Galunisertib (LY2157299)

Galunisertib is a TGF beta R1 kinase inhibitor that in vitro selectively blocks TGF beta signaling. TGF beta promotes tumor growth, suppresses the immune system and increases the ability of tumors to spread in the body.

About Merestinib (LY2801653)

Merestinib is Lilly's multi-kinase inhibitor that in vitro selectively blocks signaling of MET, MST1R (RON), AXL, and MKNK1/2.

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 has a pipeline of wholly-owned and partnered ImmTAC programs with robust clinical data, based on decades of world-leading scientific innovation in the discovery of HLA targets and T cell receptor technology and 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. Founded in 2008 originally out of Oxford University and headquartered outside Oxford, Immunocore now has more than 150 staff. Immunocore is well funded and owned by a group of long-term private investors. For more information, please visit www.immunocore.com

About Lilly Oncology

For more than fifty years, Lilly has been dedicated to delivering life-changing medicines and support to people living with cancer and those who care for them. Lilly is determined to build on this heritage and continue making life better for all those affected by cancer around the world. To learn more about Lilly's commitment to people with cancer, please visit www.LillyOncology.com.

About Eli Lilly and Company

Lilly is a global healthcare leader that unites caring with discovery to make life better for people around the world. We were founded more than a century ago by a man committed to creating high-quality medicines that meet real needs, and today we remain true to that mission in all our work. Across the globe, Lilly employees work to discover and bring life-changing medicines to those who need them, improve the understanding and management of disease, and give back to communities through

philanthropy and volunteerism. To learn more about Lilly, please visit us at www.lilly.com and newsroom.lilly.com/social-channels. P-LLY

Lilly Forward-Looking Statement

This press release contains "forward-looking statements" (as that term is defined in the United States Private Securities Litigation Reform Act of 1995) regarding the research collaboration between Immunocore and Lilly. This press release reflects Lilly's current beliefs. However, there are substantial risks and uncertainties in the process of drug research, development, and commercialization. Among other risks, there can be no guarantee that these investigational combination regimens will receive regulatory approval, or, if approved, that they will achieve intended benefits or become commercially successful products. For further discussion of these and other risks and uncertainties that could cause actual results to differ materially from Lilly's expectations, please see the company's latest Forms 10-K and 10-Q filed with the U.S. Securities and Exchange Commission. Except as required by law, Lilly undertakes no duty to update forward-looking statements.

[i] American Cancer Society. What is melanoma skin cancer? Revised March 20, 2015.

<http://www.cancer.org/cancer/skincancer-melanoma/detailedguide/melanoma-skin-cancer-what-is-melanoma> (Accessed June 25, 2015).

[ii] American Cancer Society. What are the keys statistics about melanoma skin cancer? Revised March 20, 2015.

<http://www.cancer.org/cancer/skincancer-melanoma/detailedguide/melanoma-skin-cancer-key-statistics> (Accessed June 25, 2015).

[iii] Ocular Melanoma Foundation. About Ocular Melanoma. <http://www.ocularmelanoma.org/about-om.htm> (Accessed June 19, 2015).

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