

# MedImmune and Incyte Announce Collaboration on immuno-ONCOLOGY Combination Clinical trial

AstraZeneca today announced that MedImmune, its global biologics research and development arm, has entered into a clinical study collaboration with biopharmaceutical company Incyte Corporation. The Phase I/II oncology study will evaluate the efficacy and safety of MedImmune's investigational anti-PD-L1 immune checkpoint inhibitor, MEDI4736, in combination with Incyte's oral indoleamine dioxygenase-1 (IDO1) inhibitor, INCB24360.

Both MEDI4736 and INCB24360 are investigational compounds that are part of a new class of cancer treatments known as immunotherapies, which use the body's own immune system to help fight cancer. MEDI4736 blocks the signals that help tumours avoid detection by the immune system, countering the tumour's immune-evading tactics, while INCB24360 enhances the ability of immune cells to combat the tumour. Preclinical evidence suggests that the combination of these two agents may lead to an enhanced anti-tumour immune response.

Under the terms of the agreement, MedImmune and Incyte will collaborate on a non-exclusive basis on the study, to evaluate the combination in multiple solid tumours including metastatic melanoma, non-small cell lung cancer, squamous cell carcinoma of the head and neck and pancreatic cancer. The Phase I part of the trial is expected to establish a recommended dose regimen of both MEDI4736 and INCB24360 and the Phase II part of the study will assess the safety and efficacy of the combination. Results from the study will be used to determine whether further clinical development of this combination is warranted. The study will be co-funded equally by Incyte and MedImmune and conducted by Incyte.

Dr. Bahija Jallal, Executive Vice President, MedImmune, said: "Immuno-oncology is one of the most exciting areas in our industry and we are progressing our strong pipeline as rapidly as possible. Our partnership with Incyte is further evidence of our belief that combination therapies have the potential to be one of the most effective ways of treating cancer."

"Research collaborations that evaluate combinations of novel immunotherapies across a broad range of indications have the potential to accelerate our understanding of this rapidly evolving field, to identify new areas of opportunity for immunotherapies, and to more rapidly address the unmet needs of patients with a wide range of cancers," said Hervé Hoppenot, President and Chief Executive Officer of Incyte. "For these reasons, we welcome the opportunity to work with MedImmune to explore the potential of combining MEDI4736 with INCB24360."

AstraZeneca and MedImmune have recently initiated other immuno-oncology combination trials, including MEDI4736 with IRESSA and MEDI4736 with tremelimumab. Other combination trials are planned to start imminently, demonstrating the strength and rapid progression of the company's immuno-oncology portfolio.

## About MEDI4736

MEDI4736 is an investigational human monoclonal antibody directed against programmed cell death ligand 1 (PD-L1). Signals from PD-L1 help tumours avoid detection by the immune system. MEDI4736 blocks these signals, countering the tumour's immune-evading tactics. MEDI4736 is being developed, alongside other immunotherapies (IMTs), to empower the patient's immune system and attack the cancer.

## About INCB24360

INCB24360 is an orally bioavailable small molecule inhibitor of IDO1 that has nanomolar potency in both biochemical and cellular assays, potent activity in enhancing T lymphocyte, dendritic cell and natural killer cell responses in vitro, with a high degree of selectivity. INCB24360 has been shown to be efficacious in mouse models of cancer as a single agent and in combination with cytotoxic and immunotherapy agents, and its ability to reduce tumour growth is dependent on a functional immune system - consistent with its proposed mechanism of action. A Phase I dose-escalation trial demonstrated that INCB24360 results in greater than 90 percent inhibition of IDO1 activity at generally well-tolerated doses.

INCB24360 is currently in Phase I/II development for metastatic melanoma in combination with ipilimumab (www.clinicaltrials.gov Identifier: NCT01604889) and as monotherapy for ovarian cancer (www.clinicaltrials.gov Identifier: NCT01685255). Incyte has also established a clinical agreement to combine INCB24360 with a novel anti-PD-1 immunotherapy checkpoint inhibitor.

#### About Incyte

Incyte Corporation is a Wilmington, Delaware-based biopharmaceutical company focused on the discovery, development and commercialization of proprietary small molecule drugs, primarily for oncology. For additional information on Incyte, please visit the Company's website at <u>www.incyte.com</u>.

#### About MedImmune

MedImmune is the worldwide biologics research and development arm of AstraZeneca. MedImmune is pioneering innovative research and exploring novel pathways across key therapeutic areas, including respiratory, inflammation and autoimmunity; cardiovascular and metabolic disease; oncology; neuroscience; and infection and vaccines. The MedImmune headquarters is located in Gaithersburg, Md., one of AstraZeneca's three global R&D centres. For more information, please visit <u>www.medimmune.com</u>.

## About AstraZeneca

AstraZeneca is a global, innovation-driven biopharmaceutical business that focuses on the discovery, development and commercialisation of prescription medicines, primarily for the treatment of cardiovascular, metabolic, respiratory, inflammation, autoimmune, oncology, infection and neuroscience diseases. AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide. For more information please visit: <a href="http://www.astrazeneca.com">www.astrazeneca.com</a>

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14 May 2014		

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