

Axelia Oncology Announces a Clinical Supply Agreement with Regeneron for Trial Evaluating AXA-042 in Combination with Libtayo® (cemiplimab)

Combination of First-in-Class Systemic TLR2/6 Agonist and Anti-PD-1 Monoclonal Antibody to be Studied in Patients with Advanced Solid Tumours

MELBOURNE, AUSTRALIA – 14th Feb 2025, Axelia Oncology announced today that it has entered into a clinical supply agreement with Regeneron to explore the combination of Axelia’s drug AXA-042, an innate immune modulator targeting toll-like-receptors (TLR) 2/6 and Regeneron’s PD-1 inhibitor Libtayo® (cemiplimab).

The agreement relates to Axelia’s Phase 1 clinical trial evaluating the safety and tolerability of AXA-042, a systemically delivered agonist specifically targeting TLR2/6, both as a monotherapy and in combination with Libtayo across a range of solid tumour.

“AXA-042 is a fully synthetic, systemically administered agonist targeting the TLR2/6 heterodimer which elicits a differentiated chemokine/cytokine profile with respect to other TLR agonists in the clinic.

In preclinical studies, AXA-042 efficacy was macrophage-dependent and demonstrated enhanced activity in combination with checkpoint inhibitors. These data provide a strong rationale for use of AXA-042 in cancer types unresponsive to anti-PD-1 due to myeloid cell mediated immune suppression. The monotherapy arm of the PhI trial has shown strong target engagement and impact on disease course in some patients, suggesting additional benefit may accrue with Libtayo.

We are therefore excited to have the opportunity to assess AXA-042 in combination with Regeneron’s Libtayo. Their continued investment in immuno-oncology innovation is clearly aligned with our approach to cancer immunotherapy and we are delighted to be working with them as we progress through the clinic” said **Phil Kearney PhD, CEO of Axelia Oncology**.

Under the terms of the agreement, Axelia Oncology will sponsor and be responsible for the conduct of the clinical study, which will be initiated at six clinical trial sites in Australia.

About Axelia Oncology Pty Ltd

Axelia Oncology is a biopharmaceutical company aiming to transform the treatment of checkpoint insensitive cancers through the activation of TLR2/6 engagement of the innate immune response. Axelia Oncology is developing AXA-042, a potent selective, systemically delivered, TLR2/6 agonist for solid tumour indications. AXA-042 development is based on vaccine adjuvant research from the laboratory of Professor David Jackson at the Peter Doherty Institute for Infection and Immunity, University of Melbourne.

The innate and the adaptive arms of the human immune system play a critical role in host defence, orchestrating immune recognition and elimination of pathogens or malignant cells. In oncology settings, tumours have evolved mechanisms that facilitate immune escape and promote tumour progression and resistance to checkpoint inhibitors. AXA-042 is a novel synthetic systemic TLR2/6

agonist designed to re-engage the innate immune response pathways to help overcome tumour immune escape.

For more information, please visit: www.axeliaoncology.com

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