ISA Pharmaceuticals and Scancell enter collaboration agreement for the manufacturing, development and commercialisation of Modi-1 / AMPLIVANT® combination

AMPLIVANT-Modi-1 conjugate expected to enter clinic in H1 2019
Collaboration seeks to further leverage Moditope® platform

Leiden, The Netherlands, and Oxford, UK, 15 February, 2018 -- ISA Pharmaceuticals B.V. ('ISA'), a clinical-stage immunotherapy company, and Scancell Holdings plc, ('Scancell' or the 'Company'), the developer of novel immunotherapies for the treatment of cancer, are pleased to announce that they have entered into a worldwide licensing and collaboration agreement to use ISA's AMPLIVANT® adjuvant technology for the manufacturing, development and commercialisation of Scancell's first Moditope® development candidate, Modi-1. This partnership has the potential to provide a new treatment option for patients with triple negative breast cancer, ovarian cancer, sarcomas, and other solid tumours.

Under the terms of this agreement, ISA has granted Scancell an exclusive worldwide license to manufacture, develop and commercialise the AMPLIVANT®:Modi-1 conjugate therapy and will contribute know-how and expertise related to AMPLIVANT®. Clinical studies will be conducted by Scancell and are expected to commence in H1 2019.

In return, ISA will receive an upfront payment from Scancell and is entitled to milestone and royalty fees following achievement of certain criteria as defined in the agreement. Financial details were not disclosed.

Previous pre-clinical data demonstrated that conjugation of the Modi-1 peptides to AMPLIVANT® enhances anti-tumour immune responses 10-100 fold and resulted in highly efficient tumour eradication, including protection against tumour re-challenge.

ISA's AMPLIVANT® technology can be applied to any type of targeted immunotherapy, significantly enhancing its efficacy. It is based on a proprietary and synthetic small molecule TLR1/2 ligand with enhanced immunostimulatory activity that can be chemically coupled to the respective immunotherapeutic. AMPLIVANT® conjugates allow lower dosing with higher efficacy through better dendritic cell antigen processing and presentation, as well as enhanced T cell priming.

Scancell's Moditope® platform acts by stimulating the production of CD4+ T cells using citrullinated tumour-associated peptide epitopes. This technology overcomes the immune suppression induced by tumours themselves, allowing activated T cells to seek out and kill tumour cells that would otherwise be hidden from the immune system.

"This collaboration is an important step to advance new adjuvant technologies such as AMPLIVANT® to clinical-stage programmes and bring patients better treatments," said Ronald Loggers, CEO of ISA Pharmaceuticals. "The partnership will further validate the power of AMPLIVANT® conjugates for use in therapeutic cancer vaccines that carry a variety of epitopes, including post-translationally modified epitopes such as Scancell's Moditope® products."

Cliff Holloway, CEO of Scancell, commented: "This collaboration with ISA Pharmaceuticals is an important step in the continued development and commercialisation of our first Moditope® immunotherapy, Modi-1, which has the potential to treat patients with triple negative breast cancer, ovarian cancer and sarcoma who are resistant to other immunotherapies. Our pre-clinical studies have demonstrated Modi-1 induces potent anti-tumour responses and significant improvements in survival. We believe that combining Modi-1 with an enabling adjuvant technology such as AMPLIVANT® has the potential to significantly enhance its efficacy in patients and we are looking forward to moving this important and novel therapy into the clinic in the first half of 2019."

This announcement contains inside information for the purposes of Article 7 of Regulation (EU) 596/2014 (MAR).

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About ISA Pharmaceuticals

ISA Pharmaceuticals B.V. is an immunotherapy company developing rationally designed, fully synthetic immunotherapeutics against cancer and persistent viral infections. The company has built a proprietary immunotherapy platform based on the Synthetic Long Peptide (SLP®) concept and AMPLIVANT® technology. SLP® immunotherapies are designed to fully harness and direct the body's own defenses towards fighting the disease. In December 2017, ISA Pharmaceuticals closed a clinical immuno-oncology collaboration with Regeneron to advance its SLP® lead compound ISA101, an immunotherapy targeting human papillomavirus type 16 (HPV16)-induced cancer, in combination with cemiplimab (REGN2810), a PD-1 (programmed cell death protein 1) antibody. In addition, ISA develops MyISA®, a personalized SLP® immunotherapy, targeting tumor-specific, mutation-derived neo-antigens.
For more information, please visit www.isa-pharma.com.

SLP®, AMPLIVANT® and MyISA® are registered trademarks in Europe.

About Scancell

Scancell is developing novel immunotherapies for the treatment of cancer based on its ImmunoBody® and Moditope® technology platforms.

Scancell's first ImmunoBody®, SCIB1 is being developed for the treatment of melanoma. Data from the Phase 1/2 clinical trial demonstrate that SCIB1, when used as monotherapy, has a marked effect on tumour load, produces a melanoma-specific immune response and highly encouraging survival trend without serious side effects. In patients with resected disease there is increasing evidence to suggest that SCIB1 may delay or prevent disease recurrence.

Scancell's ImmunoBody® vaccines target dendritic cells and stimulate both parts of the cellular immune system: the helper cell system where inflammation is stimulated at the tumour site and the cytotoxic T-lymphocyte or CTL response where immune system cells are primed to recognise and kill specific cells.

Pre-clinical data on a combination of SCIB1 or SCIB2 and checkpoint inhibition (blockade of the PD-1 or CTLA-4 immune checkpoint pathways) have shown enhanced tumour destruction and significantly longer survival times than when either treatment was used alone.

Scancell has also identified and patented a series of modified epitopes that stimulate the production of killer CD4+ T cells that destroy tumours with minimal toxicity. The Directors believe that the Moditope® platform could play a major role in the development of safe and effective cancer immunotherapies in the future.