



Cobra Biologics selected to manufacture plasmids for clinical trial of Scancell's COVID-19 vaccine

The collaboration will ensure GMP production of material for the Phase 1 clinical trial of Scancell's DNA vaccine against SARS-CoV-2

Oxford and Keele, UK, 2 October 2020. Cobra Biologics (Cobra), part of the Cognate BioServices family, an international CDMO manufacturer of biological materials and pharmaceuticals, and Scancell Holdings plc (Scancell), the developer of novel immunotherapies for the treatment of cancer and infectious disease, today announced that they have entered into a collaboration for Cobra to manufacture Scancell's COVID-19 vaccine. The agreement covers Good Manufacturing Practice (GMP) production of plasmid DNA needed to generate the DNA vaccine, against SARS-CoV-2, for use in a Phase 1 clinical trial in 2021 (COVIDITY). The project is funded by an Innovate UK grant awarded to the consortium between Scancell, the University of Nottingham and Trent University, as previously announced in August 2020.

Scancell's DNA vaccine will target the SARS-CoV-2 nucleocapsid (N) protein plus the key receptor binding domain of the spike (S) protein to generate both T cell responses and virus neutralising antibodies against the SARS-CoV-2 virus. This new vaccine has the potential to provide long lasting immunity against COVID-19 by generating protection not only against this strain, but also against new strains of coronavirus that may arise in the future.

The GMP production of plasmid DNA represents a crucial development in the production of a COVID-19 vaccine for use in the Phase 1 clinical trial, COVIDITY. Increasing production of plasmids to large scale and according to GMP requires management of the scale-up process to ensure plasmids are of therapeutic-grade quality. Cobra's long-established plasmid production platform along with in-house expertise will ensure the highest quality plasmids are produced for COVIDITY. The initial stages of GMP manufacture are scheduled to start imminently.

Dr Cliff Holloway, Chief Executive Officer, Scancell, commented: "Our collaboration with Cobra is critical to us moving forward with our novel SARS-CoV-2 vaccine into the planned Phase 1 clinical trial, COVIDITY. Cobra has the expertise needed to produce clinical grade plasmid at scale and we look forward to working with them to advance our vaccine and demonstrate its potential effectiveness and protection against COVID-19."

Peter Coleman, Chief Executive Officer, Cobra Biologics, added: "We are excited by this further collaboration with Scancell, with whom we share a long-standing relationship, to provide plasmid DNA for a promising new vaccine and its Phase 1 clinical trial. Our in-house expertise in quality assurance and production will ensure the delivery of GMP quality plasmid and we have great faith that Scancell's DNA vaccine will show promise against SARS-CoV-2."

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Comments to editors:



Dr Cliff Holloway, CEO, Scancell



Peter Coleman, CEO, Cobra Biologics

For high-resolution images please contact sarah.jeffery@zymecommunications.com

Contacts

Scancell Holdings plc

Dr John Chiplin, Chairman
Dr Cliff Holloway, CEO

+44 (0) 20 3727 1000

Panmure Gordon (UK) Limited (Nominated Adviser and Corporate broker)

Freddy Crossley/Emma Earl

+44 (0) 20 7886 2500

FTI Consulting

Simon Conway/Natalie Garland-Collins

+44 (0) 20 3727 1000

Cobra Biologics

Peter Coleman, Chief Executive Officer

+44 (0)1782 714181
peter.coleman@cobrabio.com

Zyme Communications

Sarah Jeffery

+44 (0)7771 730919
sarah.jeffery@zymecommunications.com

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About Cobra Biologics

www.cobrabio.com

Cobra Biologics, together with its parent company Cognate BioServices, is a leading international contract development and manufacturing organisation (CDMO) providing the highest quality development and manufacturing services for the cell and gene therapy fields, ranging from early stage development and pre-clinical services to clinical and commercial supply. Cobra and Cognate service an international customer base from its manufacturing and development facilities in the UK, Sweden, and the US.

Each of the Company's GMP approved facilities are tailored to serving our customers around the world. We offer a broad range of integrated and stand-alone contract development and manufacturing services for the clinical trial and the commercial markets.

As a trusted provider and a key partner in the drug development and commercialisation process, we take pride in our manufacturing excellence and comprehensive range of services to the pharmaceutical and biotech industries.

Cobra, through Cognate is supported by leading shareholder EW Healthcare Partners, as well as Medivate Partners, Blackrock, and a Middle Eastern Sovereign Wealth Fund, who continue supporting the business and its expansion activities.

About Scancell

www.scancell.co.uk

Scancell is developing novel immunotherapies for the treatment of cancer based on its technology platforms, ImmunoBody®, Moditope® and AvidiMab™, with four products in multiple cancer indications and development of a vaccine for COVID-19.

ImmunoBody® vaccines target dendritic cells and stimulate both CD4 and CD8 T cells with the ability to identify, target and eliminate cancer cells. These cancer vaccines have the potential to be used as monotherapy or in combination with checkpoint inhibitors and other agents. The Directors believe that this platform has the potential to enhance tumour destruction, prevent disease recurrence and extend survival.

- SCIB1, Scancell's lead product, is being developed for the treatment of metastatic melanoma. In a Phase 1/2 clinical trial, survival with SCIB1 treatment appears superior to historical survival rates, with 14 of 16 resected patients receiving 2-4 mg doses of SCIB1 surviving for more than five years (as reported in February 2018).
- SCIB2 is being developed for the treatment of non-small cell lung cancer and other solid tumours. Scancell has entered into a clinical development partnership with Cancer Research UK (CRUK) for SCIB2.

DNA vaccine against COVID-19: As research data emerges, it is becoming increasingly clear that the induction of potent and activated T cells may play a critical role in the development of long-term immunity and clearance of virus-infected cells. Initial research is underway and Scancell anticipates initiating a Phase 1 clinical trial known as COVIDITY during 2021.

Moditope® represents a completely new class of potent and selective immunotherapy agents based on stress-induced post-translational modifications (siPTM). Examples of such modifications are citrullination, an enzyme-based conversion of arginine to citrulline, and homocitrullination (or carbamylation), in which lysine residues are converted to homocitrulline. Expression of peptides containing these modifications have been demonstrated to induce potent CD4 cytotoxic T-cells to eliminate cancer. Previous pre-clinical studies have demonstrated that conjugation of these Moditope® peptides to Amplivant® enhances anti-tumour immune responses 10-100 fold and resulted in highly efficient tumour eradication, including protection against tumour recurrence.

- Modi-1 consists of two citrullinated vimentin peptides and one citrullinated enolase peptide each conjugated to Amplivant®. Vimentin and enolase peptides are highly expressed in triple negative breast, ovarian, head and neck, and renal cancer, as well as many other cancers. The Company continues to progress the Modi-1 Phase 1/2 clinical trial for regulatory submission to start the planned clinical study in the UK in the first half of 2021.

AvidiMab™ has broad potential to increase the avidity or potency of any therapeutic monoclonal antibody (mAb) including those being developed for autoimmune diseases, as well as cancer. Scancell's development pipeline includes mAbs against specific tumour-associated glycans (TaGs) with superior affinity and selectivity profiles, that have now been further engineered using the Company's AvidiMab™ technology; this confers the Scancell anti-TaG mAbs with the ability to directly kill tumour cells. The Company has entered into three non-exclusive research agreements with leading antibody technology companies to evaluate the Company's anti-TaG mAbs including those enhanced with the AvidiMab™ technology.