

»» CANCER RESEARCH UK AWARD ADENOVIRUS PROCESS DEVELOPMENT CONTRACT TO THE CBF

OXFORD UNIVERSITY CONSULTING

Cancer Research UK has awarded the University of Oxford's Clinical BioManufacturing Facility (CBF) its first commercial process development contract for the production of an adenovirus vector, for use in treating patients with recurrent ovarian cancer and hepatic metastases associated with colorectal cancer.

The CBF already possesses a distinguished history in the production of biological products for use in medicine, in particular, monoclonal antibodies and related biologics*.

Originally known as the Therapeutic Antibody Centre (TAC), the unit was a leading academic GMP (Good Manufacturing Practice) facility for the production of monoclonal antibodies and part of the Sir William Dunn School of Pathology. However, in November 2005 the unit became the CBF and joined the Nuffield Department of Clinical Medicine. Today the CBF's focus is upon the challenges faced in the production of viral vectors for use as novel recombinant vaccines and for cancer therapy. Its most notable recent success has been in the production of their first vaccine for the prevention of malaria, which is in Phase I Clinical Trials at the Centre for Clinical Vaccinology and Tropical Medicine. Two novel vaccines against hepatitis C have full approval from the Medicines and Healthcare products Regulatory Agency (MHRA), and are about to start Phase I clinical trials this summer.

CBF's objective is to provide the link between academic research and clinical drug development, thereby facilitating the rapid progress of promising biologics into clinical trials. A suite of clean rooms with supporting QC (Quality Control) laboratories and a nominated Qualified Person enables the production of master cell banks, master virus seed stocks and clinical grade material. The CBF is unusual in that it also offers a fill and finish service. It is therefore able to offer a complete service, starting with DNA, and ending up with the final clinical drug product in its finished form.

All work at the CBF is in compliance with the Manufacturer's Authorisation for Investigational Medicinal Products, known as MIA(IMP), from the MHRA which ensures that the CBF is manufacturing and releasing final clinical trial products in accordance with the European Clinical Trials Directive, 2004. The CBF's MIA(IMP) permits the importation of certain

product categories of investigational medicinal products from outside the EU, for use in clinical trials inside the European Union.

Within the field of cancer gene therapy, adenoviruses are particularly promising vectors because they achieve efficient cell cycle-independent infection, they mediate a significant inflammatory effect, and they do not integrate into cellular DNA. Indeed the first two cancer gene therapy products, now licensed in China, are both adenoviruses. Adenovirus can be used to deliver therapeutic transgenes (e.g. encoding tumour suppressors or immunostimulatory proteins) or the virus can be designed to replicate selectively within cancer cells and cause destruction of them before spreading to infect adjacent cells, so called 'virotherapy'.

The work for Cancer Research UK will involve scaling up the production methodology of an adenovirus for virotherapy, known as VTP-1, so that sufficient quantities can be produced to permit its use in two Phase I clinical trials.

Dr Shamim Kazmi-Stokes, a Principal Project Manager in Cancer Research UK's Drug Development Office, said: "We selected the CBF for this contract as our previous experience with the team during the production of a chimeric monoclonal antibody – which is now in Phase I clinical trial – was very positive. Cancer Research UK recognises that the CBF team has an excellent skill set for virus production which will be invaluable to rise to, and overcome the challenges of viral vector process development and GMP manufacture."

Oxford University Consulting (OUC) negotiated this contract with Cancer Research UK on behalf of the Clinical BioManufacturing Facility.

* Biologics are medicines produced by biological processes usually involving recombinant DNA technology.

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