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Encouraging results from the ProGem1 study of NUC-1031 in patients with advanced cancer presented at ASCO 2013

Today, at the Annual Meeting of the American Society of Clinical Oncology in Chicago, NuCana presented interim results from the Phase I study (ProGem 1) of their novel ProTide, NUC-1031. Stable disease was achieved in over half of the patients who had a range of advanced, progressive cancers.

NUC-1031 is based on the widely used anti-cancer drug, gemcitabine, but modified to overcome the three key resistance mechanisms that limit the effectiveness of gemcitabine in patients with cancer.

Today the exciting clinical results generated by NUC-1031 are reported for the first time. Eleven heavily pre-treated patients with a wide range of advanced and progressing solid tumours were given up to 6 cycles of NUC-1031, each cycle lasting 4 weeks. In over half of the patients the cancers stopped growing and they were classified as having achieved stable disease.

"The responses we are seeing with this new agent are impressive, especially in these heavily pre-treated patients with such aggressive cancers" said Dr Sarah Blagden, the Chief Investigator on the ProGem 1 study.

NUC-1031 was well tolerated with no unexpected adverse events.

The pharmacokinetic data showed that NUC-1031 is rapidly converted in the cell into the active anti-cancer agent, gemcitabine triphosphate (dFdCTP), and achieves over 30 times higher intracellular levels of the active agent than gemcitabine. In addition, the ProTide is not broken down to gemcitabine and there are much lower levels of the potentially toxic uridine metabolite, dFdU.

The ProGem1 study will continue with an expansion cohort of patients to further assess the efficacy and safety profile of NUC-1031.

Hugh Griffith, NuCana's CEO, said: "These clinical findings strongly endorse the hypothesis that ProTides are capable of overcoming key cancer resistance mechanisms. ProTides have the potential to represent a new era in cancer treatment."

About ProTides

ProTides are superior medicines based on existing nucleoside analogue drugs commonly used in the therapy of cancer and viral infections. Many patients fail to respond to the existing drugs, or develop resistance to treatment, and only a minority secures lasting benefit. ProTides have been engineered to benefit the majority of patients diagnosed with cancer. The mechanisms underlying cancer resistance are now better understood, and the innovative ProTide technology has been designed to overcome the three key resistance pathways: (i) poor activation; (ii) rapid degradation; and (iii) limited transport of the nucleoside analogues into the cancer cells. Synthesised as a monophosphate form of the nucleoside analogue, the ProTides are pre-activated, resistant to degradation and can efficiently penetrate the cell to eliminate the tumour. The ProTide technology has already been successfully validated for antiviral therapies, having been applied to a range of antiviral nucleosides by GSK, Roche, Gilead and others.



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About NUC-1031

NUC-1031 is a 'ProTide' based on a known and frequently prescribed anti-cancer drug, gemcitabine, but transformed and reengineered to overcome the three key resistance mechanisms that seriously limit the effectiveness of gemcitabine in cancer patients. NUC-1031 delivers the partially activated agent, gemcitabine monophosphate, which is rapidly converted in the cell to the active agent, gemcitabine triphosphate (dFdCTP). It is one of many molecules generated through the innovative ProTide technology platform to enhance the efficacy of conventional nucleoside analogues.

About NuCana BioMed Ltd

Headquartered in Edinburgh, UK, NuCana is a clinical stage biopharmaceutical company developing and commercialising a range of exciting, new anti-cancer medicines. With its next generation of anti-cancer agents, ProTides, NuCana is setting new benchmarks for innovative therapeutic treatments. NuCana has exclusive worldwide rights to the revolutionary ProTide technology in cancer.

Download the presented poster document at www.nucanabiomed.com/NUC1031.html