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Celleron Therapeutics Selects Syneos Health to Conduct Clinical Trial Programme for CXD101

Oxford, UK, 1 May 2018 - Celleron Therapeutics, the UK-based company developing personalised medicine for cancer patients, has today announced that the company has selected Syneos Health, a leading biopharmaceutical solutions organization, to conduct clinical trials for its lead compound CXD101 in colorectal cancer.

On 13 February, 2018 the MHRA granted Clinical Trial Authorisation (CTA) for Celleron Therapeutics to conduct a phase Ib/II trial with CXD101, the medicinal product containing N-(2-aminophenyl)-4-(1-[(1,3-dimethyl-1H-pyrzol-4-yl) [methyl]piperidin) benzamide in combination with an immune-oncology agent:

A Phase Ib/ II Trial to Assess the Safety and Efficacy of CXD101 in Combination with a PD-1 Inhibitor in Patients with Metastatic, Previously-Treated, Microsatellite-Stable Colorectal Carcinoma

The appointment of Syneos Health as the Contract Research Organization (CRO) for the trial is the next important milestone on the path to treatment of the first patient on the study - which is scheduled to occur in Q 2 /2018. Syneos Health offers leading full-service clinical services, strong site and investigator relationships and deep therapeutic expertise in oncology, including precision medicine and companion diagnostic expertise. In the last five years, the company has developed or commercialized 89 percent of novel new oncology drugs approved by the FDA and 85 percent of oncology products granted marketing authorization by the EMA. Clinical trials with Celleron's CXD101 drug are investigating not only the efficacy of the new drug but also studying a novel biomarker test, known as a companion diagnostic, to predict which patients will respond best to treatment with the drug. This approach avoids treating patients who have little chance of benefiting from the treatment so that alternative options may be considered in a timely manner.

Professor Nick La Thangue, Founder and Chief Executive of Celleron Therapeutics, and Professor of Cancer Biology in the Department of Oncology at Oxford University, commented:

"CXD101 is a potent, orally administered drug representing a class of agents that not only act directly on cancer cells but also stimulate the patient's immune system to fight the tumour. We are seeing extremely encouraging results with CXD101 and are excited to see how it performs in combination with an immune-oncology agent in a tumour indication where that agent may not have significant single agent activity – opening up new and exciting opportunities for treating aggressive types of cancer".

Dr John Whittaker, Celleron's Chief Operating Officer commented:

"Selection of a suitable clinical research organization is an important milestone for Celleron. We are very pleased to be working with Syneos Health on this exciting study. This is an important next step in pursuing Celleron's strategy to progress its proprietary targeted therapeutic, CXD101, and we look forward to working with Syneos Health in driving the clinical trial forward as fast as possible using our personalised treatment approach".

NOTES:

Celleron Therapeutics is advancing a clinical and pre-clinical pipeline of personalised therapies for different cancer indications. The company has built a proprietary platform around epigenetic control and immune modulation, providing its drugs with a two-pronged attack on cancer. Celleron's approach seeks to align the right drug with the right patient enabling a personalised approach to cancer therapy. The company is a spin-out from Oxford University and located on the Oxford Science Park.
For more information see **www.cellerontherapeutics.com**

CXD101 is Celleron Therapeutics' next generation epigenetic immune-regulator representing a class of drug that kills cancer cells by blocking certain vital functions involved in gene expression, and reactivates the patient's immune system so that cancer cells can no longer evade immune

Colorectal cancer is the second most common tumour type in women, and the third most common in men, globally. The approximate 5-year survival rate for colorectal cancer patients in the United States (all stages included) is 65% (SEER, 2016). Survival is inversely related to stage: approximate 5-year survival rates are 95% for patients with stage I disease, 60% for those with Stage III disease, and 10% for those with Stage IV (metastatic) disease.

A subset of colorectal cancers is characterized with deficient DNA mismatch repair (dMMR or microsatellite instability, MSI). Detection of MSI has become important for treatment for metastatic colorectal cancers, as those with MSI-H expression respond favourably to immune checkpoint inhibition, a type of biologic therapy. These tumours tend to have high expression of checkpoint proteins, including programmed death 1 (PD-1) and programmed death ligand 1 (PDL1), which interfere with the body's anti-tumour T-cell response. By disabling these proteins, checkpoint inhibitors (such as pembrolizumab and nivolumab) allow the immune system to function properly, and T-cells to kill tumour cells. Where patients have a normal Mismatch Repair proficient expression, the microsatellite phenotype is stable (MSS) and the tumour is thus resistant to checkpoint inhibition.