CELLERON THERAPEUTICS

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Celleron Therapeutics reports over 2-year survival of cancer patient treated with zabadinostat monotherapy

Oxford UK, 7 April 2022 – Celleron Therapeutics, the UK-based company developing personalised medicines for cancer patients, announced today a Phase I clinical trial cancer patient who continues to benefit from continuous zabadinostat therapy for over 2 years.

CXD101-0901 is a clinical trial sponsored by Oxford University Hospitals NHS Foundation Trust, with support from Celleron Therapeutics. It is an open-label, Phase I study in patients with various advanced tumours where zabadinostat (formerly CXD101) is administered orally, twice daily, for 5 days, repeated every 3 weeks. The study began with a dose escalation phase to determine the maximum tolerated dose. Dose expansion was then opened at a recommended dose of 40mg daily. A total of 17 patients were treated in the dose expansion, which was closed to enrolment in 2019.

As of March 2022, one patient continues to receive zabadinostat monotherapy, having started treatment in December 2019. This patient has tolerated the drug well, experiencing few drug-related side effects with over 2 years of therapy. In terms of clinical response, the patient's tumour has been effectively controlled during this extended period of time.

Dr Graham Collins, Principal Investigator and Haematology Consultant at the Oxford University Hospitals, commented: *"It's really gratifying to have a patient with high-risk cancer responding so well for so long to an oral and well tolerated treatment".*

Professor David Kerr, Chief Medical Officer of Celleron Therapeutics, commented: *"We are excited by this encouraging long-term response to monotherapy, which adds to the continuing evidence that zabadinostat is a clinically viable drug with wide utility in clinically unmet disease. It is of interest that this subject has been able to tolerate dosing for more than 2 years, without experiencing any serious adverse drug reactions. We expect to further develop our understanding of this response with our upcoming large-scale clinical trial".*

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About Celleron Therapeutics Limited

Celleron Therapeutics is a biopharma advancing a clinical and pre-clinical pipeline of precision therapies for different cancer indications. The company is a spin-out from Oxford University and located on the Oxford Science Park, UK. Celleron Therapeutics 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.

Celleron Therapeutics' focus is on those cancers where there is still an unmet need for long-term disease control. It is hoped that not only will patients volunteering for our clinical trials benefit directly, but the results from these studies will ultimately allow the general use of more effective, safer medicines. Our goal is not only to treat cancer but improve quality of life during therapy by reduction of side effects.

Celleron has global license partnerships with Astra Zeneca and Roche. The company secured investment in 2016 from a consortium of South Korean investors; and in 2020 span out an affiliate company, SynOx Therapeutics.

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About Zabadinostsat

Zabadinostat (formerly 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 (histone–deacetylase [HDAC] inhibitor) and reactivates the patient's immune system so that cancer cells can no longer evade immune recognition.

Celleron have completed a Phase II clinical study testing the effect of zabadinostat in combination with the immune checkpoint inhibitor (ICI) nivolumab in microsatellite stable colorectal cancer, which typically does not respond to ICI agents alone (the CAROSELL Study). The therapeutic strategy rests on compelling pre-clinical results which provide novel insights into how zabadinostat and ICI drugs work together to re-engage recognition of tumours by the immune system, colloquially, to turn 'cold tumours 'hot'.

The study enrolled 55 previously-treated patients from five UK academic centres, and demonstrated disease control and objective response rates of 48% and 9% respectively; and that the ICI combination was very well tolerated from a safety perspective.

As the next step towards commercialisation, a global Phase III clinical trial of zabadinostat, as MSS CRC combination therapy with an immune check-point inhibitor is planned to start in 2022.

The European Medicines Agency (EMA) has previously granted zabadinostat.

Orphan Drug Designation as single agent therapy, based upon early-phase trial efficacy seen in relapsed or refractory Peripheral T-Cell Lymphoma (PTCL) patients. A PTCL Phase II trial is scheduled to start 2022 in China.