CELLERON THERAPEUTICS

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Celleron Therapeutics announces approval of China IND Registration Clinical Trial with partner Nuance Biotech

Oxford, UK, 20 January 2021 – Celleron Therapeutics, the Oxford-based UK company developing novel medicines to treat cancer, today announced that with its Chinese partner, Nuance Biotech Ltd, the company has received approval from the Chinese Center for Drug Evaluation for an IND registrational trial to develop CXD101 in patients suffering from peripheral T-cell lymphoma (PTCL).

Previously, a Phase I trial in multiple tumour types demonstrated that CXD101 has an acceptable safety profile, and a promising signal for efficacy was observed in multiple tumour types, which led to the grant of EU Orphan Drug Designation in PTCL. A bridging study conducted in Hong Kong began in 2020 to evaluate the safety and pharmacokinetics in Chinese patients with multiple tumour types.

A Chinese Investigational New Drug (CIND) application is intended to support a Chinese New Drug Application (NDA) leading to marketing approval for the drug. This has now been approved by the Center for Drug Evaluation (CDE), which opens the way for Celleron and Nuance to the roll out a Phase Ib/II clinical trial in PTCL commencing late 2021.
Under the terms of the partnership agreements, Nuance Biotech received a license to develop and commercialise Celleron CXD101, in indications of high unmet medical need, in return for significant royalties and milestone payments relating to the development and commercialization of the products in China.

Professor David Kerr, Chief Medical Officer of Celleron Therapeutics, commented: *"This is a major milestone in the development of CXD101, which we know to be active in diverse lymphomas. We look forward to beginning the trial and working with Nuance in deploying CXD101 in China".*

Professor Nick La Thangue, Chief Executive Officer of Celleron Therapeutics, commented: *"Approval from the Chinese CDE for this trial is a massively important step in continuing the successful growth of Celleron Therapeutics as a commercially focused cancer company".*

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 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.
Celleron has a global license partnership with Astra Zeneca. The company secured investment from a consortium of Asian investors; and in 2020 span-out its first subsidiary, SynOx Therapeutics, with a $44 million investment committed from a leading syndicate of international investors.

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About Nuance Biotech

Nuance Biotech is a leading China based biotech company based in Shanghai, focussed on commercial, regulatory and development stage assets and run by an experienced China based management team with a strong track record. Nuance is backed a leading global tier 1 investor with more than USD 3 billion under management in China through Matrix Partners. The company strategy and approach allows for a highly scalable commercial and drug development model.

About CXD101

CXD101 is a next generation epigenetic immune-regulator representing a class of drug targeting histone deacetylase 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 recognition. The European Medicines Agency (EMA) has previously granted CXD101 Orphan Drug Designation as single agent therapy, based upon early-phase trial efficacy seen in relapsed or refractory PTCL patients. Celleron Therapeutics is also leading a Phase Ib/II clinical trial in diffuse large B-cell lymphoma (DLBCL) patients who have failed on chemotherapy, called PLACARD, which is testing the combined effect of CXD101 and pembrolizumab.

About peripheral T-cell lymphoma

PTCL is a Non-Hodgkin's Lymphoma (NHL) which covers a group of rare and often aggressive cancers that result from the proliferation of mature T-cells. Together they form a heterogeneous group which is categorized into subtypes according to clinical, morphological, immunophenotypic, and in some instances molecular characteristics. The three most common subtypes of peripheral T-cell lymphoma are peripheral T-cell lymphoma not otherwise specified (PTCL-NOS), anaplastic large-cell lymphoma (ALCL), and angioimmunoblastic T-cell lymphoma (AITL). PTCL is predominantly diagnosed in adults and is more common among men. The prognosis for most subtypes is poor, as the disease often follows an aggressive course and therefore requires rapid treatment. The majority of patients have a 5- year survival of less than 30%. The disease remains clinically unmet.