CellAct Pharma Presents Interim Phase 2 Data Showing CAP7.1 Initial Efficacy in Biliary Tract Cancers at ASCO GI

Dortmund, Germany, January 25, 2016 – CellAct Pharma, a developer of innovative treatments for cancer, announced today preliminary data from its ongoing randomized, multicenter Phase 2 clinical study of CAP7.1 in biliary tract cancers at the American Society of Clinical Oncology 2016 Gastrointestinal Cancers Symposium in San Francisco. The data showed that patients treated with CAP7.1, an adapted version of the well-established anticancer agent etoposide, exhibited initial efficacy in this difficult to treat patient population, with 56% of patients meeting the primary objective of disease control, including tumour shrinkages. CAP7.1 treated patients displayed an estimated 1-year survival rate of 41%, which is approximately 20% higher compared with historical controls.

CAP7.1, an inactive precursor of the anticancer drug etoposide, remains inactive until it meets an enzyme in the body called carboxylesterase, which is present in high concentrations in the gastrointestinal tract and is particularly active in tumour cells. This focused release of etoposide via CAP7.1 into cancer cells enables relatively highly doses to be administered with good safety and tolerability profile. CAP7.1 holds EU Orphan designation in the treatment of biliary tract cancer.

"This initial Phase 2 data with CAP7.1 is very encouraging. More than half of patients met the primary objective of disease control, which includes stable disease and tumor shrinkages," stated Nalân Utku, M.D., Chief Executive Officer of CellAct.

Study Details
Patients in the treatment arm were subjected to a 3-week cycle with CAP7.1 on days 1-5 until progression. At progression the control arm (best supportive care) patients were allowed to cross over to the CAP7.1 arm. Commonly observed drug related adverse events were various events of infection, alopecia, fatigue, nausea and abdominal pain, all of which were generally well managed. A total of 18 of expected 50 patients were included in this initial analysis.

A previous clinical phase I study in 19 adults with multiple and heavily pre-treated solid tumors treated with CAP7.1 showed stable disease and partial response in 11 patients over six months. The longest survival times of up to two years were seen in patients with biliary tract and non-small cell lung cancers.

About CellAct Pharma
CellAct Pharma is focused on the development of innovative therapeutics for the treatment of cancer. CellAct's drug candidates target and modulate human molecules that have specific functions in tumor growth. A first-in-class small molecule compound, CAP7.1 is currently enrolling patients in randomized, multicenter clinical Phase II studies for the treatment of biliary tract cancers, non-small cell lung cancers and small cell lung cancers. In addition to venture capital funding, CellAct has received a €0.7 million grant from the German ministry for education and science (Bmbf) to support this program. For further information visit www.cellact.eu.

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