CellAct Pharma Phase 2 CAP7.1 Population Pharmacokinetic Data Supports Efficacy Results in Biliary Tract Cancers

Data Published at ASCO Annual Meeting

Dortmund, Germany, and Chicago, IL, USA, June 3, 2016 – CellAct Pharma, a developer of innovative treatments for cancer, announced today that population pharmacokinetic (PK) data from a phase 2 study of CAP7.1 supports efficacy findings in biliary tract cancer patients. CAP7.1 is a newly designed prodrug of the well-established anticancer agent etoposide, converted by carboxylesterases into etoposide in selected tissues. Analysis of the population PK indicated higher blood concentrations of etoposide resulted in the majority of patients maintaining an increase in tumor size below 20%. Data were published in conjunction with the 52nd Annual Meeting of the American Society for Clinical Oncology (ASCO) in Chicago (Abstract e15602).

"Population pharmacokinetics is an important consideration in the drug development process as it helps to explain the variable effects of certain inter patient characteristics, such as age, body weight and co-medication, can have on a drug's efficacy and safety. The data presented at ASCO will help in determining a standard dosing regimen for CAP7.1," explained Nalân Utku, MD, PhD, MDRA, Chief Executive Officer of CellAct Pharma. "These population PK data provide additional support to the results from our Phase 2 with CAP7.1, where encouragingly, planned interim analysis showed that more than half of therapy refractory, advanced stage biliary tract cancer patients met the primary objective of disease control, as presented at the ASCO GI Meeting in San Francisco."

Study Details

Data for the population PK model was analyzed from a total of 434 observations taken from 39 patients from Phase 1 and 2 studies. Using PK modeling software, etoposide $AUC_{0\text{-}24h}$, c_{max} and c_{min} for each biliary cancer patient were simulated and compared with the individual changes in total target lesion (TTL) size. A higher $AUC_{0\text{-}24h}$ was found to be associated with a lower increase in TTL size (R^2=0.172). Out of all patients for which PK information was available, 50% maintained a TTL size increase below 20%. This compared to 80% of patients with an 24hAUC > 120 h ug/mL who maintained a TTL size increase below 20%. Similarly, a higher c_{max} (R^2=0.177) or c_{min} (R^2=0.11) were associated with a larger effect on TTL size.

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 being evaluated in randomized, multicenter clinical Phase 2 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.

Contacts:
Nalân Utku, MD, PhD, MDRA
Chief Executive Officer
CellAct Pharma
Tel: +49 231 9742 6350
n.utku@cellact.eu

Mike Sinclair
Partner
Halsin Partners
Tel: +44 20 7318 2955
msinclair@halsin.com