Kantonsspital St.Gallen

A phase I/Ib, open-label, multi-center dose escalation study of NIS793 in combination with PDR001 in adult patients with advanced malignancies (CNIS793X2101)

This is a first-in-human (FIH), open label, phase I/Ib, multi-center study which consists of:

- a dose escalation part of NIS793 as single agent and in combination with PDR001.

Patients treated with NIS793 single agent will switch to NIS793 in combination with PDR001 either upon disease progression or after 2 cycles whichever is earlier. Dose es-calation of NIS793 in combination with PDR001 will com-mence after two dose levels in the dose escalation with single agent have been tested. Once the two dose levels of NIS793 single agent have been evaluated, dose escalation is planned to continue in the combination arm only. Once the Maximum Tolerated Dose (MTD) and/or Recommended Dose for Expansion (RDE) of NIS793 in combination with PDR001 is determined, patients with solid tumors in selected indications will commence in dose expansion.

- a dose expansion part of NIS793 in combination with PDR001.

NIS793 and PDR001 will be administered i.v. until a patient experiences unacceptable toxicity, progressive disease as per irRC, death, is lost to follow-up or treatment is discon-tinued at the discretion of the Investigator or the patient. Patients should not discontinue treatment based on pro-gressive disease per Response Evaluation Criteria in Solid Tumors (RECIST) v1.1 unless clinical deterioration or

increase in tumor markers is observed.

project members	
keywords	dose escalation, combination with PDR001, with advanced malignancies
type of project	clinical studies
status	ongoing - recruiting phase
start of project	2019
end of project	2021
study design	Phase I
Swissmedic notification number	2018DR1087
responsible person	Prof. Dr. med. Markus Jörger