Kantonsspital St.Gallen

A Phase 2, multi-center, open label study of NIR178 in combination with PDR001 in patients with selected ad-vanced solid tumors and non-Hodgkin lymphoma

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This is a multi-center, open label, phase 2 study to evaluate efficacy of the NIR178 and PDR001 combination in NSCLC, other solid tumors, and diffuse large B-cell lymphoma (DLBCL). The study has three parts: part 1: Multi-arm Bayesian adaptive signal finding design in solid tumors and diffuse large B cell lymphoma (DLBCL); part 2: NIR178 schedule exploration in NSCLC; part 3: Further evaluation of intermittent dosing schedules of NIR178 in combination with PDR001 in additional tumor types, if part 2 identifies an intermittent dosing schedule of NIR178 as warranting further exploration. Parts 1 and 2 will enroll in parallel. Part 3 will be opened based on the results from part 2. Patients enrolled in this study will receive NIR178 160mg either BID continuously or based on the assigned intermittent schedule within 60 minutes prior to PDR001 infusion. PDR001 will be administered via IV infusion over 30 minutes once every 4 weeks. Each treatment cycle is 28 days. Patients will receive treatment with the combination until disease progression (assessed by investigator per immunerelated response criteria (irRC) (Appendix 3 or Cheson 2014), unacceptable toxicity, death or discontinuation from study treatment for any other reason (e.g., withdrawal of consent, start of a new anti-neoplastic therapy or at the discretion of the investigator), otherwise known as End of Treatment. Adult patients with histologically documented advanced or metastatic solid tumors (e.g. non-small cell lung cancer (NSCLC), renal cell carcinoma (RCC), pancreatic cancer, urothelial cancer, head and neck cancer, diffuse large B-cell lymphoma (DLBCL), microsatellite stable (MSS) colon cancer, triple negative breast cancer (TNBC) or melanoma will be en-rolled. All patients must have disease amenable to biopsy and must be willing to undergo biopsy at screening/baseline, and during the course of study treatment as per protocol requirement. For parts 1 and 2, patients must not have received prior Immunotherapy. For part 3, patients in the NSCLC group must have received prior immunotherapy.

type of project	clinical studies
status	ongoing - recruiting phase
start of project	2017
end of project	2019

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