

DTXL-TNP (designated BIND-014) is currently undergoing evaluation in a phase 1 clinical trial (NCT01300533), where DTXL-TNP is given by intravenous infusion every 3 weeks to cancer patients. The main eligibility criteria are ≥ 18 years old; advanced or metastatic cancer for which no standard or curative therapy exists; measurable or evaluable disease per RECIST version 1.1; Eastern Cooperative Oncology Group performance status of 0 or 1; and life expectancy of >12 weeks. The clinical trial uses a standard dose-escalation design in which patients are assigned to cohorts receiving progressively higher doses until a dose is reached at which dose-limiting toxicities are observed. Single patient cohorts are enrolled at low-dose levels; subsequent dose levels are enrolling three-patient cohorts. Blood samples for PK analysis are analyzed for total DTXL concentration with LC-MS. All patients provide written informed consent before participation in the study. Three patients were given 30 mg/m² of DTXL-TNP by intravenous infusion and blood was drawn at various times.