

Clinical State	Year	No. Of Patients	Indication	Region	Type
Pilot / Blind/Man	2001-2003	30	Multiple Tumors	Germany	Initial Pilot
Phase IIa Proof of Concept	2003-2004	53	RESprotect Prevention of Chemoresistance	Pancreatic Cancer Germany	Extended
Phase IIb Finding Study	2004-2006	22	Pancreatic Cancer	Germany	Dose
Phase I Healthy volunteers	2007-2008	18	-	USA	Food Effect

Summary of Clinical Trials with RP101

Phase II/III 2007-2010 153 Pancreatic Cancer USA, Europe, South Korea, Asia, Africa
 Blind/Placebo controlled; endpoint = overall survival
 Phase II 2009-2010 Not yet defined Pancreatic Cancer South Korea, Asia
 Proof of Concept in Asians
 Several clinical studies have been conducted with RP101 tablets in oncology. In a pilot phase I study, 31 patients with various tumor types were treated with multiple chemotherapeutic agents and RP101. In this study with 5 tumor entities (lung, breast, ovary, pancreas) it was shown that RP101 could be combined with various cytotoxic drugs: as mono-chemotherapy-regime vinorelbine, gemcitabine, docetaxel, epirubicin; as poly-chemotherapy-regime carboplatin + gemcitabin + vinorelbine, doxorubicin + endoxan + vincristine, carboplatin + vinorelbine, carboplatin + paclitaxel, carboplatin + docetaxel, carboplatin + etoposide, carboplatin + irinotecane, cisplatin + gemcitabine, epirubicin + endoxan.

Safety population: 83 patients (Pilot and Phase I Studies)

This study was extended to treat 13 patients with advanced pancreatic carcinoma (Stage III and IV). In an open label study, patients received gemcitabine + cisplatin + RP101 (500 mg/day) in 5-day cycles. A dose ranging study of RP101 and gemcitabine was completed at three sites in Germany. In this study, 22 patients were treated with a fixed dose of gemcitabine (1000 mg/m² for 3 days) and varying doses of RP101 (500-1000 mg/day) for 12 days of a 28 day cycle.

Food effect studies with healthy volunteers showed that it is profitable not to eat immediately before taking RP101 tablets.

A phase II/III study with 153 pancreas cancer patients is currently running worldwide in 55 sites.

Clinical Studies - Overview