Summary of Clinical Trials with RP101

Clinical State	Year	No. Of Patients	Indication	Region	Type
Pilot / First Study in Man	2001-2003	30	Multiple Tumors	Germany	Initial Pilot
Phase IIa Proof of Concept Study	2003-2004	13	Pancreatic Cancer	Germany	Extended
Phase IIb Finding Study	2004-2006	22	Pancreatic Cancer	Germany	Dose
Phase I Healthy volunteers Study	2007-2008	18	-	USA	Food Effect
Phase IIb (ongoing)	2007-2010	167	Pancreatic Cancer	USA, Europe, South America	Double blind, placebo controlled; endpoint = overall survival

Several clinical studies have been conducted with RP101 tablets in oncology. In a pilot phase 1 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 vinorelbin, 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.

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.

Clinical Studies - Overview

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