



Safety

RP101 binds to the heat shock protein Hsp27 and inhibits its association with other proteins. These molecules (e.g. caspase 3) play a critical role in the prevention/inhibition of apoptosis in tumor cells. Deregulation of apoptosis is specific for tumor cells and has not been described in normal cells. Over-expression of Hsp27 is a mechanism of tumor cells for evasion of cytotoxic drug induced apoptosis resulting in resistance against chemotherapy. RP101 prevents this chemoresistance.

Consequently, the data of our clinical studies indicate that Gemcitabine hematotoxicity is not aggravated by co-administration of RP101. It can be concluded that observed toxicities can be attributed to the cytotoxic agent Gemcitabine. There are no additional toxicities attributable to RP101. Moreover, the quality of life (Karnofsky-Index) after the 6th or latest cycle of RP101 + chemotherapy treatment is better than before the first cycle in most cases.

Supportive evidence comes from the fact that RP101 has been used for more than 20 years in thousands of patients as virostatic drug without showing noteworthy side effects.