



EU Orphan Drug Designation for RP101

RP101 Granted European Orphan Drug Designation for Pancreatic Cancer

In January 2010, RP101 was granted the Orphan Drug designation for the adjunct treatment of pancreatic cancer by the European Medicines Agency (EMA). This designation will allow RESprotect a ten-year period of market exclusivity once RP101 is approved. The Orphan Drug designation is intended to provide incentives to drug and biologics suppliers to develop and supply drugs for the treatment of rare diseases, currently defined as diseases that affect no more than 5 in 10,000 people in the EU. U.S. orphan drug designation for RP101 was already granted by the U.S. Food and Drug Administration (FDA) in 2009.

RESprotect has recently been qualified for the SME (small and medium enterprise) status by the EMA, which will - in combination with the orphan drug status of RP101 - facilitate an accelerated approval at low costs.

About RP101: RP101's potential efficacy for treating cancer patients was discovered by the founder of RESprotect, Prof. Fahrig. RP101 has been evaluated in combination with cytotoxic agents such as gemcitabine which is used to treat pancreatic, lung, ovarian and breast cancer patients. Although approved in several European countries for antiviral indications, RP101's potential efficacy to combat chemoresistance and improve chemosensitivity constitutes a new clinical use for RP101 which is protected by three use patents of RESprotect. In two separate, unrelated small clinical trials with late-stage pancreatic cancer patients, RP101 was used in combination with gemcitabine, the current standard of care, or gemcitabine + cisplatin. The results were published in 2006 (Fahrig et al., *Anti-Cancer Drugs* 17, 2006, 1045-56). In summary, RP101 co-treatment considerably enhanced median survival.

About RESprotect: RESprotect GmbH is a privately owned Biotech Company located in Dresden/Germany. RESprotect is focusing on the inhibition of chemoresistance and the enhancement of chemosensitivity of tumors. Chemogenomics, the approach of Resprotect, focuses on the application of small synthetic molecules, which elicit favourable phenotypic changes. The combination with genomic tools concentrating on specific biological pathways allows a better understanding of the broader effect of a drug. Thus, it is possible to discover drugs that target the cause of a disease rather than its symptoms. RESprotect's compounds are given additionally to standard chemotherapy. In contrast to the well known efforts to circumvent or decrease existing chemoresistance, RESprotect's approach is unique.