

AustCancer Licenses Phase I/II Pancreatic Cancer Drug

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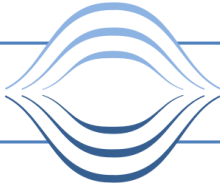
- 1) **Completed successful Phase I/II clinical pilot study**
- 2) **Strong response in metastasized pancreatic cancer patients**
- 3) **US Phase IIb/III pivotal trial to begin in 2005**

Australian Cancer Technology ("AustCancer") (ASX:ACU) announced today that it had signed an agreement with the German company RESprotect GmbH, to acquire the North American licence to a developmental pancreatic cancer drug. The drug, RP101 has demonstrated promising results in a clinical Phase I/II pilot study. AustCancer has developed an accelerated clinical trial program for RP101 which would include application to the US FDA for Orphan Drug status.

RP101 is targeted at preventing cells from developing a resistance to chemotherapy, one of the most challenging areas facing oncologists. RP101 would be used as a co-treatment with cytostatic drugs to give a broader range of chemotherapy treatment options, thereby extending survival periods and improving quality of life for the cancer patients.

A Phase I/II pilot clinical study with 30 patients in German clinics over five tumour types (metastasized breast, metastasized ovarian, non small cell lung cancer, small cell lung cancer and metastasized pancreatic cancer) was completed in 2003 with different chemotherapy agents. An enlargement of the pilot trial, in 13 metastasized pancreatic cancer patients is still running. An interim analysis of this trial shows strong patient responses, including total remission in two patients as measured by tumour markers, and partial remission of the primary tumour in three patients as measured by computerised tomography or sonography. Moreover, in two other patients, remissions of liver or lung metastases could be observed. According to the interim analysis, it seems likely that RP101 co-treatment significantly enhances survival time, remissions, time to progression and response to chemotherapy.

RESprotect's founder and major shareholder, geneticist Professor Dr. Rudolf Fahrig commented that "the



results from the Phase I/II pilot trials are extremely promising and show particular efficacy in pancreatic cancer patients. This is probably due to the fact that when tested in vitro with tumour cells, RP101 has a major effect in down-regulating the oncogene STAT3, and the DNA-repair gene APEX, which are over-expressed in pancreatic carcinoma."

AustCancer's Chairman, Dr Roger Aston said, "While the patient numbers in the previous pancreatic trials were small, the results appear significant. We believe that the drug may offer new or significant improvements for pancreatic cancer by satisfying unmet medical needs, and therefore might qualify for Orphan Drug status when we lodge the IND (Investigative New Drug application) in the US next year".

A repeat Phase I/II dose finding study is expected to begin in Germany in 6-8 weeks and will be funded by AustCancer. The trial will be over two centres with 22 pancreatic patients and managed by a Swiss CRO. Following the results of this trial, which is expected to last 6 months, AustCancer will commence a pivotal Phase IIb/III trial in the US in 2005 and has already held discussions with two leading US cancer centres who are interested in running the trial. AustCancer has commenced the regulatory due diligence in the US and expects to lodge a submission with the FDA next year.

Cancer of the pancreas is the fifth leading cause of cancer deaths with mean survival time for locally metastasized pancreatic cancer of 4-6 months with a 2-year survival rate of 10%. There are approximately 20,000 new pancreatic cancer patients in the US each year.

RESprotect is closely associated with the Universities of Leipzig, Munich, Vienna and The Technical University of Dresden. The intellectual property for this development came from the Fraunhofer Society of Munich, a leader in applied research in Europe. Professor Fahrig has agreed to join the AustCancer Scientific Advisory Board.

As part of the agreement, AustCancer will also acquire 10% of the capital of RESprotect GmbH.

Bio-IB, LLC, a New York based healthcare investment bank, acted as an advisor to Australian Cancer Technology on this transaction.

ENDS

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About Australian Cancer Technology

Listed on the Australian Stock Exchange (code: ACU) Australian Cancer Technology is a broadly based international oncology company developing a portfolio of high quality oncology-related projects that are at various stages of commercialisation. Cash generating businesses will provide the funds to exploit the potential of its leading products and to introduce promising pre-clinical and Phase I projects into the development pipeline. Its leading edge PentrysTM anti-cancer vaccine successfully completed Phase I and Phase I/IIa trials at St. Vincent's Hospital Sydney and is undergoing a comprehensive Phase IIb trial with prostate cancer patients at three leading Melbourne institutions. Its US subsidiary, revisysTM, is launching a range of medical nutritionals designed by leading US scientists for people with special needs, including those undergoing cancer treatment. The company is also broadening its cancer therapeutic development pipeline and has recently announced the acquisition of US based Galenica Pharmaceuticals, whose immune enhancing adjuvants are being used in three Phase I and II cancer trials and will be used in a number of other forthcoming clinical trials in association with Memorial Sloan Kettering Cancer Centre in New York. AustCancer has established a Level 1 ADR stock program in the US, trading under the code of AUCJY.

www.austcancer.com.au

About RESprotect

RESprotect GmbH is a privately owned biotechnology company located in Dresden Germany. RESprotect is focusing on the inhibition of chemoresistance and the enhancement of chemosensitivity. In contrast to the well known efforts to circumvent or decrease existing chemoresistance, this basic approach is unrivalled.

Chemogenomics, the approach of RESprotect, focuses on the application of small synthetic molecules which elicit favorable phenotypic changes. The combination with genomic tools concentrating on specific biological pathways allows a better understanding of the broader effect of the drug. By doing so, 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. Chemotherapy relies upon the induction of apoptosis of tumor cells, which is the main anti-cancer mechanism. One major problem in chemotherapeutic treatment is the induction of chemoresistance, which antagonizes the apoptosis of cancer cells. The chemogenomics approach of RESprotect resulted in the identification of a number of validated targets contributing to the development of chemoresistance by antagonizing apoptosis. RP101, the Company's first small molecule drug candidate, suppresses the over-expression of apoptosis-antagonizing gene products induced by cytostatic drug treatment.

www.resprotect.de

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