

AKT-SER473 PHOSPHORYLATION AS A MARKER FOR PREDICTING TAXANE CHEMOTHERAPY OUTCOME

SUMMARY

The National Institute of Health, National Cancer Institute is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize a marker for predicting taxane chemotherapy outcome.

REFERENCE NUMBER

E-191-2009

PRODUCT TYPE

- Diagnostics

KEYWORDS

- Biomarkers
- immunohistochemistry
- pAkt
- Companion Diagnostics
- Diagnostic Assays
- Cancer

COLLABORATION OPPORTUNITY

This invention is available for licensing.

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DESCRIPTION OF TECHNOLOGY

Over the past decades, taxanes such as paclitaxel and docetaxel have emerged as effective chemotherapy agents for breast cancer and other malignancies. Taxanes are effective in many patients, however, not all patients benefit from this type of chemotherapy. A significant need remains for a means of predicting clinical outcome from taxane-based chemotherapy.

Akt, a serine/threonine kinase that can block apoptosis, has been implicated in the regulation of microtubule dynamics and organization. Akt phosphorylation and its transducing downstream events

play a central role in cell survival and cell cycle progression at the G2/M transition. Paclitaxel or docetaxel inhibits Akt-Ser473 phosphorylation (pAkt) and induces mitotic arrest. Therefore, taxanes may cause more damage to tumor cells that are dependent on pAkt for survival and cell cycle progression, significantly impacting treatment outcome.

Researchers at the National Cancer Institute, NIH, have identified pAkt as having predictive significance for paclitaxel chemotherapy outcome in patients with early stage breast cancer. The researchers have developed an immunohistochemistry method for determining pAkt status with appropriate controls for assay performance and cutoff for pAkt positivity. They also discovered methods of correlating pAkt expression with clinical outcome (disease-free survival and overall survival). pAkt is a novel predictive marker of taxane chemotherapy, and can be applied to indicate which patients should receive taxane-based chemotherapy.

POTENTIAL COMMERCIAL APPLICATIONS

A kit for identifying pAkt-positive tumors in surgical tumor specimens or tumor biopsies prior to treatment (adjuvant, neoadjuvant therapy or therapy for metastatic disease); and methods for predicting clinical outcome from taxane chemotherapy.

COMPETITIVE ADVANTAGES

pAkt is a useful clinical predictive marker to determine which patients should or should not receive taxane-based chemotherapy for cancer. Determining pAkt status would allow patients with pAkt-positive tumors to elect taxane therapy for whom are likely to benefit, and allow patients with pAkt-negative tumors for whom are unlikely to benefit to be spared from taxane therapy as well as toxicity, and earlier use of other therapies that could be more effective.

PATENT STATUS

- **U.S. Issued:** U.S. Provisional Application No. 61/180,558 filed 22 May 2009