CANCER RESEARCH

Clinical Research

PHY906 in hepatocellular carcinoma

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Abstract

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Traditional botanical formulations in combination with conventional chemotherapeutics may prove to be a powerful approach to reduce toxicity and improve clinical outcome. *In vivo* studies indicate that PHY906, a traditional Chinese formulation, can reduce chemo-induced gastrointestinal toxicity while simultaneously enhancing the therapeutic efficacy of a broad-spectrum of common anticancer agents in various cancer models.

Co-administration of PHY906 with a variety of chemotherapeutic agents in animal models does not appear to alter either the pharmacokinetic profile of the chemotherapeutic agents or their respective metabolites. PHY906 pharmacokinetics is still under investigation. Only a small fraction of the phytochemical components are orally absorbed and are detectable in PHY906-treated animal serum.

PHY906 has inhibitory activity on multi-drug resistant protein (MDR) and CYP450. The presence of these inhibitions facilitated the oral uptake of chemotherapeutic agents. Examination of the tumor tissues and compounds involved suggest that the integrity of the blood vessel and the pathways of HIF-α and Fos/Juk transcription were affected.

I*n vitro* studies also reveal that PHY906 has inhibitory activities against NF-κB and matrix metalloproteases (MMPs), which are possible contributors to the

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enhancement of the antitumor action of chemotherapeutic agents. Possible mechanisms of action for the reduction of gastrointestinal toxicity by PHY906 are the inhibition of Tachykinin NK-1, Opiate δ receptors, and acetylcholine esterase based. The *in vivo* mechanism of action of PHY906 and its active compounds involved is currently under study.

PHY906 is currently being investigated in a phase I/II, U.S. multicenter, open-label, dose-escalation, safety and efficacy study in combination with capecitabine in patients with unresectable HCC. The clinical endpoints of this study include (1) time to disease progression, (2) overall survival time, and (3) quality of life. Three dose levels of PHY906 + capecitabine were evaluated in phase I: PHY906 1000 mg BID + capecitabine 1000 mg/m^2 BID; PHY906 600 mg BID + capecitabine 750 mg/m^2 BID; and PHY906 800 mg BID + capecitabine 750 mg/m^2 BID. The final dosing schedule was chosen for the phase II portion of the study. Preliminary results suggest that the quality of life of patients being treated with the combination is improved when compared to historical controls studying capecitabine alone. There is also no evidence that PHY906 causes drug-induced toxicity nor reduces capecitabine antitumor activity.

Plans are currently underway in the U.S. to investigate the effect of PHY906 in combination with capecitabine in patients with locally advanced or metastatic pancreatic carcinoma. In addition, based on in vivo pre-clinical studies, a second trial will investigate the combination of PHY906 and gemcitabine in this same patient population.

Footnotes

- 98th AACR Annual Meeting-- Apr 14-18, 2007; Los Angeles, CA

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