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GASTROINTESTINAL (NONCOLORECTAL) CANCER

A phase I/II study of PHY906 plus capecitabine (CAP) in patients (pts) with advanced pancreatic cancer (APC)

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Abstract

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Background: PHY906 is a formulation of traditional Chinese medicine botanicals: *Scutellaria baicalensis Georgi*, *Glycyrrhiza uralensis Fisch.*, *Ziziphus jujuba Mill.*, and *Paeonia lactiflora Palla*. Our preclinical studies have indicated that PHY906 has synergistic anti-tumor activity with CAP in PANC-1 cell lines (Saif MW. ASCO 2007) and is a potent inhibitor of NF-κB. Studies in other tumor types have shown that PHY906 may reduce chemotherapy-induced GI toxicities, especially diarrhea and does not alter pharmacokinetics of CAP. These data have prompted phase I/II evaluation of safety and tolerability of a dose intense wkly (7/7) schedule for CAP plus PHY906. **Methods:** During phase I study, pts with advanced solid tumors (ST) who failed standard therapy or for which no standard therapy exists, ECOG PS ≤ 2, and adequate organ function were enrolled. Pts received PHY906 800 mg BID (D1–4) with escalating doses of CAP (1,000 mg/m^2 →1,250 mg/m^2 → 1,500 mg/m^2 → 1,750 mg/m^2 BID on D1 -7) followed by 7 days rest, until MTD was reached. During phase II study, pts with gemcitabine-refractory APC will be enrolled. Toxicity was assessed per NCI CTCAE v3.0 and response per RECIST q 6 wks. **Results:** To date, 23 pts [18 M/5 F; median age of 64 yr;

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WE RECOMMEND

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M. W. Saif, J Clin Oncol, 2016

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M. Heller et al., J Clin Oncol, 2016

A phase I study of gemcitabine plus dasatinib (GD) or gemcitabine plus dasatinib plus cetuximab (GDC) in refractory solid tumors

4 AST/ALT]. No DLTs were seen at higher doses. However, delayed toxicities were seen at 1,750 mg/m^2. Therefore, additional 3 pts have been added at 1,500 mg/m^2 before moving onto the phase II part. Delayed grade ≥ 3 toxicities included hand-foot syndrome (n=3), nausea (n=3), mucositis (n=1), diarrhea (n=2), and hyperglycemia (n=2). One pt with cholangiocarcinoma had PR at cycle 3 and 9 pts experienced SD lasting ≥ 6 weeks (7 pancreas; 2 colon). **Conclusions:** Combination of CAP and PHY906 has acceptable toxicity in pts with ST. Phase II study will assess efficacy and quality of life in gemcitabine-refractory APC pts. Correlative chemokine (IL-2, IL-4, IL-5, IL-10, TNF-α, IFN-γ) levels, as surrogates for NF- κB expression, will be quantified by Cytometric Bead Array to help elucidate PHY906 mode of action.

Author Disclosure

Employment or Leadership	Consultant or Advisory Role	Stock Ownership	Honoraria	Research	Te
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