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GASTROINTESTINAL (NONCOLORECTAL) CANCER

Phase II study of PHY906 plus capecitabine (CAP) in pts with gemcitabine-refractory pancreatic cancer (PC) and measurement of cytokines.

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Abstract

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Background: Oral CAP offers convenience as a palliative chemotherapeutic option, however, diarrhea and HFS may compromise its efficacy. Pts in USA cannot tolerate CAP 1,250 mg/m^2 BID D1-14 without experiencing toxicities. PHY906, a traditional Chinese botanical formula has shown synergistic anti-tumor activity with CAP as well as cytoprotective anti-diarrheal effect in preclinical and phase I studies (ASCO 2007, 2008). These data provide a strong rationale for extending this combination into PC.

Methods: PC pts with prior gemcitabine received CAP 1,500 mg/m^2 BID D1-7 and PHY906 800 mg/m^2 BID D1-4 q 2 wks. AEs were assessed per NCI CTCAE v3.0 and response per RECIST q 6 wks. Primary objective was OS and secondary aim to determine effect of PHY906 on cytokines and chemokines including IL-2, IL-4, IL-5, IL-6, IL-10, MCP-1, TNF-a, IFN-g, VEGF, FGF-B, GM-CSF, G-CSF using a cytometric bead array assay.

Results: Twenty-five pts were enrolled: 25 received study drug (evaluable for safety); 23 received at least 1 cycle (evaluable for efficacy). Median age was 60yr (range 45-84), 10 F and 15 M, with a median ECOG PS of 1 (range 0-2). Predominant AEs included grade 3 diarrhea (n = 3), grade 3 fatigue (n = 3) and grade 3 HFS (n = 1). Among 23 pts, 2 achieved PR (9%), 10 had stable disease (43%) resulting in

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disease control rate of 52%. All intent-to-treat pts reached mPFS of 10 wks (r: 0.4-51) and mOS of 12 wks (r: 0.4-63). For 18 pts who received > = 2 cycles, mPFS was 13 wks and mOS 31 wks. 9-mth survival rate was 22%. Preliminary correlative studies showed that none of the cytokines except serum IL-6 was reversely correlated with survival. QOL data is currently under evaluation.

Conclusions: This is the first clinical study to evaluate a botanical drug PHY906 plus CAP in PC. Our results suggest that PHY906 can increase therapeutic index of CAP by reducing diarrhea and HFS. This combination appears a safe and feasible salvage therapy after gemcitabine failure and warrants further investigation in a randomized study against CAP. Recent studies have indicated role of IL-6 in tumor progression and tumor cachexia, suggesting a need to investigate its relation to pathophysiology of PC and development of anti-IL-6 therapeutics.

Author Disclosure

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PhytoCeutica	PhytoCeutica		Bayer, Bristol-Myers Squibb, Genentech, Novartis, Roche, sanofi-aventis	Enzon, Merck PhytoCeutica Roche, Taiho Pharmaceutic

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