Updated analysis of weekly nab-Paclitaxel (P)+ Gemcitabine (G) with metastatic pancreatic cancer (MPC): Phase I / II trial

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Background: In the phase III study for MPC (MPACT study), nab-P+ G significantly improved overall survival (OS) compared with G (median OS, 8.5 months (M) vs 6.7 M; Hazard Ratio, 0.72; P < 0.001) with tolerable toxicity profile [Von Hoff D, et al., 2013]. Regarding the Japanese phase I/II study for MPC, we previously reported overall response rate (ORR); 44.1%, median progression free survival; 5.6 M and median survival time had not been reached (median follow-up was 4.7 M) as of the primary analysis [M. Ikeda, et al., JSMO2014 Abst 50706]. We report safety and efficacy update.

Methods: Eligible criteria were definitive histologically or cytologically confirmed MPC, no prior therapy, one or more measurable metastatic tumors (RECIST ver1.1), ECOG PS 0-1, age 20-79, adequate organ functions. Patients (pts) received nab-P 125 mg/m2, followed by G 1000 mg/m2 on days 1, 8, and 15 every 4 weeks. The primary endpoint was ORR according to RECIST by the independent review.

Results: A total of 34 pts were enrolled between November 2012 and July 2013. Pts characteristics were as follows: median age 64 years; PS0 21 pts, PS1 13 pts; tumor location: head 14 pts, body 7 pts, tail 10 pts, body tail 3 pts. The median OS was 13.5 M (The median follow-up was 13.6 M (range, 12.5-19.8 M)). At the 12 M follow-up, the main adverse drug reactions (ADR) of grade 3/4 were neutropenia (71%), anemia (15%), thrombocytopenia (15%), febrile neutropenia (6%), and peripheral neuropathy (12%). There were no treatment-related deaths. Thirty three pts had discontinued study treatment; the most common reason was progressive disease (81.8%). Pts of 97% received subsequent therapy: S-1 based 85%, G based 6%.

Conclusions: The efficacy of nab-P+ G for MPC is significant, with median OS 13.5 M. The ADR profiles in this study were as tolerable as in MPACT study. Our result suggested nab-P+ G can be one of the first-line standard treatments in Japanese pts with MPC. Clinical trial information: JapicCTI-121987.