

MM-398 added to standard treatment shows survival benefit in mets pancreatic cancer

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Adding the novel MM-398 to standard treatment for metastatic pancreatic cancer patients who have already received gemcitabine improves survival, researchers said at the ESMO 16th World Congress on Gastrointestinal Cancer in Barcelona.

"Patients with metastatic pancreatic cancer or pancreatic cancer in general have very limited options," said study author Andrea Wang-Gillam, assistant professor in the Division of Oncology at Washington University in St. Louis, USA. "These <u>patients</u> just simply don't do well. This was a positive trial and will provide a new treatment option for patients with metastatic pancreatic cancer."

One of the biggest challenges in pancreatic cancer is drug delivery. "MM-398 (nal-IRI) is a nanoliposomal irinotecan: this delivery system allows longer drug exposure in the circulation and more accumulation of the drug and its active metabolite SN38 at the tumour site," Wang-Gillam said. "MM-398 therefore generates higher anti-tumour activity and is more effective than conventional irinotecan alone in the preclinical setting."

The phase II study had demonstrated the anti-tumour activity of MM-398 monotherapy as second-line treatment in patients with metastatic pancreatic cancer refractory to gemcitabine [1].

The current NAPOLI-1 trial was a global randomised phase III trial at more than 100 sites. There were 3 treatment arms: MM-398, standard



treatment with 5-fluorouracil (5FU)/leucovorin, and MM-398 plus 5FU/leucovorin. The trial included 417 patients who had progressed or received prior gemcitabine-based therapy. The primary endpoint was overall survival.

Overall survival was significantly improved with the combination therapy of MM-398 plus 5FU/leucovorin compared to 5FU/leucovorin alone. Median overall survival was 6.1 months in the MM-398 plus 5FU/leucovorin group compared to 4.2 months in the group receiving standard treatment with 5FU/leucovorin alone (hazard ratio [HR]=0.67, p=0.012). Progression-free survival also improved significantly, from 1.5 months with the standard therapy to 3.1 months in patients receiving MM-398 plus 5FU/leucovorin (HR=0.56, p

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