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A randomized, open-label phase II study of nanoliposomal irinotecan (nal-IRI)-containing regimens versus nab-paclitaxel plus gemcitabine in patients with previously

untreated metastatic pancreatic adenocarcinoma (mPAC).

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Abstract Disclosures

Abstract

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Background: Two combination chemotherapy regimens have emerged as standard of care options for first-line treatment of mPAC: 5-fluorouracil (5-FU)/leucovorin (LV) + irinotecan + oxaliplatin (FOLFIRINOX), and nab-paclitaxel + gemcitabine. Nal-IRI (MM-398) is a nanoliposomal formulation of irinotecan. In a randomized phase 3 study (NAPOLI-1), of patients with mPAC who had been previously treated with gemcitabine-based therapy, nal-IRI + 5-FU/LV demonstrated its safety and significant clinical activity, increasing overall survival (OS) and progression-free survival (PFS) relative to 5-FU/LV. The goal of this current study is to determine the preliminary safety and

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efficacy of nal-IRI+ + 5-FU/LV with or without oxaliplatin as compared to nab-paclitaxel + gemcitabine in previously untreated patients with mPAC. **Methods:** This open-label, phase 2 comparative study will be conducted in two parts. Part 1 is a safety run-in of a nal-IRI+5-FU/LV + oxaliplatin regimen. The safety run-in will enroll small cohorts of patients following a traditional 3 + 3 dose escalation design to confirm the target dose of oxaliplatin (n = ~6-18). The primary objective of Part 1 is the safety and tolerability of nal-IRI + 5FU/LV + oxaliplatin. Part 2 is a randomized, efficacy study of a nal-IRI + 5-FU/LV + oxaliplatin regimen (Arm 1), the nal-IRI + 5-FU/LV combination that previously demonstrated efficacy in the NAPOLI-1 trial (Arm 2), versus a nab-paclitaxel + gemcitabine control arm (Arm 3) (n = ~156-168). The primary objective of Part 2 is to assess the efficacy of nal-IRI-containing regimens in first-line mPAC patients compared to nab-paclitaxel + gemcitabine using the progression-free survival (PFS) rate at 24 weeks as the primary endpoint. Secondary of part 1 is a PK study and Part 2 secondary endpoints will include OS, PFS, objective response rate (per RECIST, v1.1), decrease in CA19-9 levels and quality of life assessments. Clinical trial information: NCT02551991.

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