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Interim analysis of a phase II study of dose-modified FOLFIRINOX (mFOLFIRINOX) in locally advanced (LAPC) and metastatic pancreatic cancer (MPC).

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Abstract

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Background: Although FOLFIRINOX is superior to gemcitabine in MPC, the regimen is associated with significant toxicities (Conroy et al. *N Engl J Med* 2011;364:1817). In our prior retrospective analysis, efficacy was not compromised by dose attenuations of FOLFIRINOX (Gunturu et al. *Med Oncol* 2013;30:361). Based on this analysis, we are conducting a prospective phase II open label study to evaluate the efficacy & tolerability of mFOLFIRINOX in pts with advanced pancreatic cancer (PC). **Methods:** Previously untreated pts with MPC or LAPC received mFOLFIRINOX with 25% dose reductions of irinotecan & bolus 5-FU given every two wks until progression, unacceptable toxicity, or surgical resection. All pts received prophylactic pegfilgrastim. FDG-PET scans were obtained at baseline & after 2 cycles. CAT scans were obtained after every 4 cycles. Toxicities & response rate (RR) were compared to historical data reported by Conroy.

Results: 53 pts with ECOG PS ≤1 have been enrolled to date between 11/11 and 08/13, Pt characteristics: LAPC 22; MPC 31; median age 62 yrs (range 46-86); male 30. Median # of cycles was 8 (range 1-21). Grade 3/4 toxicities were: anemia, febrile neutropenia (FN) & peripheral sensory neuropathy (PSN) – 3.8% each; ALT increased & thromboembolism – 5.7% each; diarrhea 7.5%; fatigue 11.3%; neutropenia 17%; thrombopenia 11.3% & vomiting 1.9%. Anemia (p< 0.04), FN (p<0.04), PSN (p<0.04) and vomiting (p<0.02) were significantly decreased compared to historical data (Conroy). Response by RECIST (CR+PR) in 26 evaluable pts with MPC was 29% (0 CR, 9 PR, 14 SD, 3 PD) & similar to historical data (31.6%; p 0.85). 6/13 evaluable pts with LAPC underwent resection (46%).13/36 pts evaluable for PET response had a >50% decrease in SUV(max)(36%). Evaluation for OS & PFS is ongoing. **Conclusions:** Findings from our interim analysis suggests that mFOLFIRINOX, given along with prophylactic pegfilgrastim is associated with a similar RR and improved tolerability compared to full dose FOLFIRINOX in advanced PC. In pts with LAPC, neoadjuvant FOLFIRINOX appears to have substantial activity with 46% of evaluable pts undergoing

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