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Abstract CT214: Paricalcitol addition to chemotherapy in patients with previously untreated metastatic pancreatic ductal adenocarcinoma (PINBALL)

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Abstract

Background Vitamin D agonism has been shown in preclinical studies to decrease the production of collagen, decrease myeloid derived suppressor cells, and decrease regulatory T cells in pancreatic ductal adenocarcinoma (PDAC). Paricalcitol is a vitamin D analog used for vitamin D replacement for those with secondary hyperparathyroidism. Two individuals with PDAC who had been developed resistance gemcitabine based combination therapy had shown clinical benefit with the addition of paricalcitol. This clinical study was done to study the effect of adding paricalcitol to individuals with metastatic PDAC receiving gemcitabine based combination therapy (NCT04054362, NCT03415854) .

Methods Adults with a histologically- or cytologically-confirmed diagnosis of metastatic PDAC and who were previously untreated were eligible. Individuals received gemcitabine based combination- either gemcitabine plus nab-paclitaxel or gemcitabine plus nab-paclitaxel and cisplatin and had to either demonstrate progressive or stable disease. Paricalcitol was given at a fixed dose of 25 mcg IV three days a week. The combination continued until either disease progression or poor tolerance. The primary objective was to determine the clinical benefit of adding paricalcitol to gemcitabine based combination therapy for metastatic PDAC. Secondary objectives included assessing safety and pharmacodynamic through patient biopsies.

Results A total of 34 patients were enrolled across two sites. 16 patients received paricalcitol. The overall response rate was 0% (CR, PR). Disease control rate at 9 weeks was 21.4% (CR+PR+ SD). PFS upon addition of paricalcitol was 1.6 months. OS upon addition of paricalcitol was 4.8 months. Grade 3/4 AE's attributed to paricalcitol include 13% thrombocytopenia; 19% anemia; 6% transaminitis; 6% pleural effusion; 6% ascites- all grade 3.

Conclusions The addition of paricalcitol demonstrated evidence of limited clinical benefit in individuals with metastatic PDAC receiving front-line gemcitabine based therapy. Paricalcitol was generally well tolerated. Tumor analysis is ongoing. Addition studies utilizing prospective treatment of paricalcitol for front line treatment of mPDAC are ongoing (NCT03520790). Trial funding provided by SU2C, CRUK, Lustgarten Foundation, and AACR.

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