

(OS), impaired function, body weight and pain scores. After a 1-14 day screening period, visits occur weekly until 12 weeks (with implantation at week 4) followed by visits at week 16 and then 8-weekly intervals until subjects reach documented progression of disease criteria for LPFS and PFS. OS will be determined by 8-weekly medical record review and/or telephone contact until subject death or 104 weeks after last subject enrolment. Pain will be assessed via Numerical Rating Scale and the EORTC QLQ PAN-26.

Results:

Conclusion: Conclusion: This study will help determine the safety and shed further light on the efficacy of ³²P microparticles in patients with locally advanced, unresectable pancreatic cancer treated with contemporary chemotherapy regimens.

P – 229 PanCO: design of an open label, single arm pilot study of OncoSil™ in subjects with unresectable locally advanced pancreatic adenocarcinoma, given in combination with standard chemotherapy

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Introduction: Background: Patients with locally advanced, unresectable pancreatic cancer are at risk of both local and distant progression. Standard chemoradiation results in improved local control. However, contemporary studies have failed to demonstrate a survival advantage. The effectiveness of the radiation treatment is limited by the risk of serious toxicities to dose-limiting organs, particularly the gastrointestinal tract. Furthermore, multiple radiation treatment sessions are required, daily over 5 weeks. Brachytherapy with ³²P Microparticles (OncoSil™) permits a greater radiation dose to be delivered in a highly-targeted manner directly into a tumour in a single implantation whilst sparing surrounding healthy tissue and critical organs. A previous trial, DB2-201, investigating OncoSil™ in combination with gemcitabine found the treatment to be safe and well-tolerated with encouraging tumour response and control. The proposed pilot study will evaluate the safety of OncoSil™ in this patient population.

Methods: Methods: In this open-label, single arm pilot study, 20 subjects with histologically or cytologically proven unresectable pancreatic adenocarcinoma with locally advanced disease will be enrolled in at least 8 Australian, UK, and European sites. ³²P microparticles are implanted using endoscopic-guided ultrasound following leucovorin + 5-FU + irinotecan + oxaliplatin (FOLFIRINOX) or gemcitabine+nab-paclitaxel per local prescribing standards. The intended average absorbed radiation dose per treated tumor is 100 Gy (±20%). The primary endpoint is safety and tolerability; secondary endpoints include local progression-free survival (LPFS), PFS, overall survival