Microparticles in a patient population undergoing standard chemotherapy for unresectable LAPC.

Methods: Eligible patients were allocated to receive either gemcitabine+nab-paclitaxel or FOLFIRINOX by physician choice. P-32 implantation took place during the 4th or 5th week following the initiation of chemotherapy. P-32 was implanted directly into the pancreatic tumour via EUS guidance, using a fine needle aspiration (FNA) needle. Each patient's dose was calculated from the tumour volume where the absorbed dose of P-32 to the tumour was calculated to equal 100 Gy. Diffusion pattern of the P-32 suspension following implantation was assessed by EUS and by bremsstrahlung SPECT/CT imaging. Chemotherapy was continued after the implantation. Safety data was collected weekly and toxicity was graded using the Common Terminology Criteria for Adverse Events (CTCAE). Centrally-read CT scans were conducted every 8 weeks to assess response defined as complete response [CR], partial response [PR], and stable disease [SD]) rate, according to RECIST 1.1 criteria. FDG-PET scans were performed at baseline and at week 12.

Results: Data is reported on the first 15 implanted patients (10 males and 5 females, median age 65 years [range 54-73]) up to week 16 of follow up. At 16 weeks, the objective response rate was 20% - PR in 3/15 patients. The local disease control rate (CR, PR and SD) was 87% - either PR or SD in 13/15 patients. Median change in tumour volume from baseline to week 16 was -33% (range +36% to -72%). Total lesion glycolysis (TLG) as measured via FDG-PET scan showed a median reduction of 52% (range +45% to -100%) from baseline to week 12. The EUS-guided implantation was carried out successfully in all patients and without any complications. By week 16, 223 adverse events (AEs) were reported. Twenty-four Grade 3 AEs (11%) and 5 (2%) Grade 4 toxicities were reported. The most common AEs of Grade 3 and 4 severity were neutropenia (6), anaemia (2), constipation (2), vomiting (2) and fatigue (2). None of the G3 and G4 AEs were attributable to the device or the implantation procedure.

Conclusion: Early data indicates that the use of EUS-guided implantation of P-32 is highly feasible, well tolerated and has an acceptable safety profile in combination with standard first-line chemotherapy for LAPC. Preliminary data shows evidence of tumour regression and local disease control. These results, however, warrant further evaluation. The clinical trial is ongoing and additional safety and efficacy data will be presented. ClinicalTrials.gov Identifier: NCT03003078. Acknowledgement: Nab-paclitaxel was supported by Specialised Therapeutics Australia Pty Ltd.

P – 141 PanCO: An open-label, single-arm pilot study of Oncosil™ in patients with unresectable locally advanced pancreatic adenocarcinoma in combination with FOLFIRINOX or gemcitabine+nab-paclitaxel chemotherapies

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Introduction: Locally advanced pancreatic cancer (LAPC) is associated with a poor prognosis. Current standard treatment is limited to chemotherapy or chemo-radiotherapy. Novel treatment approaches are crucial in attempting to combat this unmet medical need. Phosphorus-32 (P-32) Microparticles is a brachytherapy device that implants a predetermined dose of the beta radiation emitting isotope (P-32) directly into pancreatic tumours via endoscopic ultrasound (EUS) guidance. The presented data are early results from an ongoing international, multi-institutional, single-arm pilot study. The study objective is to determine the safety and efficacy of P-32