PanCO: An Open Label, Single Arm Pilot Study of Oncosil™, Administered to Study Participants with Unresectable Locally Advanced Pancreatic Adenocarcinoma, Given in Combination with Folfirinox or Gemcitabine+Nab-Paclitaxel Chemotherapies

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Introduction
Locally advanced pancreatic cancer (LAPC) accounts for 36% to 45% of unresectable disease1 and is associated with a poor prognosis. Median survival is 6-12 months without chemotherapy. Conventional radiotherapy (CRT) is used to treat patients with advanced disease and is a weakly effective and generally unrewarding treatment. However, conventional radiotherapy is limited by the amount of radiation that can be safely delivered to the target tissue (superficial tumors) to avoid unacceptable toxicity. Novel treatment approaches are crucial in attempting to combat the current medical need. Phosphorus-32 (P-32) is a monoisotopic radioisotope with a 14.8-day half-life. Radioactive decay of P-32 (β decay) provides an effect similar to a high-dose bolus of external beam radiation therapy (EBRT) in the range of 10-20 Gy, but on a much shorter time scale (1-2 h) which is not absorbed by healthy tissue. It offers an attractive alternative for local treatment of cancerous pancreatic cells, when it is implanted directly into the tumor. Several case reports illustrate its local control efficacy, but are lacking in randomized controlled trials.

Safety and Tolerability
A total of 319 patients were included in Week 16 of the study. 20 patients were implanted up to the 9th of January 2018. Twenty (20) patients were deemed to have evaluable PET scan assessments at Baseline and at Week 12. Overall survival (OS) was determined at the last subject death, or 104 weeks after last subject enrollment. Of the 20 patients enrolled, 17 of whom also had evaluable PET scan assessments at Baseline and at Week 12. Overall survival (OS) was determined at the last subject death, or 104 weeks after last subject enrollment. Of the 20 patients enrolled, 17 of whom also had evaluable PET scan assessments at Baseline and at Week 12.

Results
Baseline patient demographics and characteristics are shown in Table 1 for the first 20 patients enrolled in the Oncosil™ device up to the 6th week of implantation. Adverse events are mostly reported AEs. The majority of the AEs of Grade 1 or 2 were uncomplicated procedures. The most common reported AEs of Grade 3 or 4 were neutropenia, nausea, vomiting, and thrombocytopenia.

Efficacy
Radiotherapeutic Response
PET scan assessment
PET scan were scored by a central reader. 17 of 20 patients had evaluable PET scan assessments at Baseline and at Week 12. Lesion Tumour Glucoses (LUG) as measured by PET scan showed a median reduction from Week 1 to Week 12. G1B (range: +4% to -10%). Metabolic remission and absence of defined viable necrotic hepatic mass were reported. PET scans were scored as 0-4, with 0 indicating no change, 1 indicating less than 10%, 2 indicating 10-25%, 3 indicating 25-50% and 4 indicating greater than 50%.

Local Disease Control Rate and Best Response Rate

Study design

Figure 1. Study design

Figure 2. Percentage change in tumour volume from Baseline to Week 16 (N = 20)

Table 1. Patient Demographics and Baseline Characteristics (N = 20)

Table 2. Most commonly reported AEs (N = 20)

Table 3. Local Disease Control Rate and Best Response Rate

Table 4. Endoscopist Assessment of Implantation Procedure

Table 5. Device performance according to SPECT-CT Brennanstrahlung imaging reports (N = 20)

Conclusions

The purpose of this interim analysis is to report on the early observations and performance of the Oncosil™ device when implanted intratumourally using EUS. 17 of 20 patients had evaluable PET scan assessments at Baseline and at Week 12. Overall survival (OS) was determined at the last subject death, or 104 weeks after last subject enrollment. The clinical trial is ongoing and additional safety and efficacy data will be presented.

References

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Disclosures

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