OSPREY

ONCOSIL PANCREATIC CANCER POST-MARKETING CLINICAL REGISTRY

A post-market, global, multicentre, observational, prospective registry of data recorded from patients who are treated using the OncoSil™ device

Purpose:
To collect and assess the performance and safety of the OncoSil™ device when used within the approved indication of unresectable, locally advanced pancreatic cancer, in combination with gemcitabine-based chemotherapy, within a real-world observational registry.

Location/Participating Centres:
10-20 centres across the following countries anticipated to participate:

- Belgium
- Germany
- Israel
- Italy
- Portugal
- Spain
- Turkey
- United Kingdom

Duration:
- Recruitment is anticipated to take five years
- Data will be collected over a prescribed 12-month period from enrolment, and the cohort is then followed to death or 24 months from date of the last enrolled patient implanted with OncoSil™
- Registry therefore expected to run for a seven-year period

Data Collection:
Registry will collect the following real-world observational data and information via medical record review:

- Safety and tolerability of OncoSil™ within a routine clinical setting
- OncoSil™ implantation performance
- Overall survival (OS)
- Target (implanted) tumour response (local and distant)
- Progression-free survival (PFS)
- Surgical resection rates and outcome

Registry Treatment:
OncoSil™ device in combination with gemcitabine-based chemotherapy

Patient Number:
500 enrolled patients implanted with OncoSil™

Registry Sponsor:
OncoSil Medical Ltd.

This is a summary provided for information purposes. Please refer to the OncoSil™ System Instructions For Use and the OSPREY Registry Protocol (OSPREY01) for additional information.

Registry Patient Population

Every patient who is intended to undergo implantation of the OncoSil™ device will be approached by the Treating Physician to consent to participate in the OSPREY Patient Registry.*

The OncoSil™ device will be used within the approved indication of unresectable, locally advanced pancreatic cancer, in combination with gemcitabine-based chemotherapy.

*Patients who choose not to consent to participate in the OSPREY Patient Registry will not be excluded from being treated with the OncoSil™ device.

INCLUSION CRITERIA

- Confirmed unresectable locally advanced pancreatic cancer (LAPC)
- Undergo OncoSil™ implantation at an eligible treatment facility
- Completed and signed the Patient Informed Consent Form (PICF) for the OSPREY Patient Registry
- Pancreatic target tumour recommended size: <7 cm (longest diameter) and <110 cc (volume)
- A clinically acceptable ECOG performance status
- ≥ 18 years of age at screening
- Due to commence gemcitabine-based chemotherapy (per Standard-of-Care or according to the approved prescribing schedule) post Registry enrolment
- Adequate biochemical tests, coagulation profile, haematological, renal, and hepatic function as determined by the Treating Physician

EXCLUSION CRITERIA

- Patient Informed Consent Form (PICF) for the OSPREY Patient Registry has not been completed and signed
- Patients treated with OncoSil™ within an approved interventional clinical study (company or investigator-sponsored)
- Evidence of distant metastases based on review of baseline CT scan
- More than one primary lesion
- In the opinion of the Treating Physician, endoscopic ultrasound (EUS) directed implantation posing undue patient risk. This includes:
  - Where previous endoscopic ultrasound-guided fine-needle aspiration (EUS-FNA) was considered technically too difficult to perform
  - Imaging demonstrates multiple collateral vessels surrounding or adjacent to the target tumour within the pancreas
  - Presence (or significant risk) of varices near to the target tumour
- Evidence of radiographic invasion into stomach or duodenum (if not certain, confirmation must be obtained prior to enrolment)
- In the setting of recent, clinically significant pancreatitis, implantation is not recommended
- Pregnant or intending to commence a pregnancy within 12 months of the intended date of implantation, or breastfeeding
- Known history of hypersensitivity to silicon or phosphorous, or any of the OncoSil™ components

Patient selection will be in accordance with the OncoSil™ System Instructions for Use.

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INTENDED USE/INDICATIONS FOR USE: OncoSil™ is intended for intratumoural implantation into a pancreatic tumour via injection under endoscopic ultrasound guidance. OncoSil™ is indicated for the treatment of patients with locally advanced unresectable pancreatic cancer, in combination with gemcitabine-based chemotherapy. The OncoSil™ System is supplied sterile and is intended for single-patient, single-use.

This information is intended for healthcare professionals only. All medical treatments carry benefits and risks. For safety related information, please refer to the OncoSil™ System Instructions for Use. OncoSil™ is a registered trademark of OncoSil Medical Ltd. Suite 503, Level 5, 15 Blue Street, North Sydney, NSW 2060 Australia. PR10-EMAP-0921.

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