OSPREY

ONCOSIL PANCREATIC CANCER POST-MARKETING CLINICAL REGISTRY

A post-market, 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:

Centres across EU and the UK will participate in the OSPREY Patient Registry.

Duration:

- Recruitment is anticipated to take five years
- Data will be collected over a prescribed 12-month period from enrolment
- Patients will be 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.

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

- Patients eligible for and undergo OncoSil™ implantation at an eligible treatment facility according to the approved Instructions for Use, as part of their clinical care
- Patients who have completed and signed the Patient Informed Consent Form (PICF) for the OSPREY Patient Registry

EXCLUSION CRITERIA

- Patients participating in an interventional clinical study (company or investigator-sponsored)
- Patients using an investigational agent at the time of enrolment

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

This is a summary provided for information purposes. Please refer to the OncoSil™ System Instructions For Use, the OSPREY Registry Protocol (OSPREY01) and ClinicalTrials.gov (identifier: NCT04493632) for additional information.

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