



ASX Announcement

29 October 2019

OncoSil AGM CEO Presentation

Sydney, Australia – 29 October 2019: OncoSil Medical Ltd (ASX: OSL) (**OncoSil** or the **Company**), a medical device company focused on localised treatments for patients with pancreatic and liver cancer, has released its CEO presentation for the Annual General Meeting of OncoSil shareholders to be held at 11:00am AEDT today.

-ENDS-

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About OncoSil

OncoSil Medical is a medical device company seeking to advance radiation for cancer patients. OncoSil Medical's lead product, OncoSil™ is a targeted radioactive isotope (Phosphorus-32), implanted directly into a patient's pancreatic tumours via an endoscopic ultrasound.

Treatment with the OncoSil™ is intended to deliver more concentrated and localised beta radiation compared to external beam radiation. OncoSil Medical has conducted four clinical studies with encouraging results on tolerability, safety and efficacy. A CE Mark application to commercially sell OncoSil™ in the European Union (EU) is under review.

The U.S Food and Drug Administration granted an Investigational Device Exemption (IDE) in July 2016 with approval to conduct a clinical study of the OncoSil™ device. The aim of the study will be to collect safety and effectiveness data required to support a Premarket Approval (PMA) application.

An Investigational Device Exemption (IDE) has been granted by the United States Food and Drug Administration (FDA) to conduct a clinical study of the OncoSil™ device aimed at supporting a PMA approval. Pancreatic cancer is typically diagnosed at a later stage, when there is a poor prognosis for long-term survival. The World Cancer Research Fund estimated that in 2012, 338,000 people globally were diagnosed with pancreatic cancer. The prognosis for patients diagnosed with pancreatic cancer, regardless of stage, is generally poor; the relative five-year survival rate for all stages combined is approximately 5%. The estimated world- wide market opportunity for OncoSil™ in pancreatic cancer

exceeds \$1b.

Hepatocellular carcinoma (HCC) or liver cancer, is the 6th most common cancer in the world with 782,000 new cases diagnosed in 2012. While hepatocellular carcinoma can be treated by surgery or transplantation, the majority of patients with HCC have disease which is too advanced for surgery and their survival ranges from a few months to two or more years. The value of the hepatocellular cancer market is expected to triple in size to \$1.4b by 2019.

Forward Looking Statements

This document contains certain forward-looking statements, relating to OncoSil's business, which can be identified by the use of forward-looking terminology such as "promising", "plans", "anticipated", "will", "project", "believe", "forecast", "expected", "estimated", "targeting", "aiming", "set to", "potential", "seeking to", "goal", "could provide", "intends", "is being developed", "could be", "on track", or similar expressions, or by express or implied discussions regarding potential filings or marketing approvals, or potential future sales of product candidates. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no assurance that any existing or future regulatory filings will satisfy the FDA and other authorities' requirements regarding any one or more product candidates nor can there be any assurance that such product candidates will be approved by any authorities for sale in any market or that they will reach any particular level of sales. In particular, management's expectations regarding the approval and commercialisation of the product candidates could be affected by, among other things, unexpected trial results, including additional analysis of existing data, and new data; unexpected regulatory actions or delays, or government regulation generally; our ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; government, industry, and general public pricing pressures; and additional factors that involve significant risks and uncertainties about our products, product candidates, financial results and business prospects. Should one or more of these risks or uncertainties materialise, or should underlying assumptions prove incorrect, actual results may vary materially from those described herein as anticipated, believed, estimated or expected. OncoSil Medical is providing this information as of the date of this document and does not assume any obligation to update any forward-looking statements contained in this document as a result of new information, future events or developments or otherwise.



oncosil

MEDICAL
ASX:OSL

Advancing Pancreatic cancer treatment – changing the prognosis

CEO AGM Presentation

29 October 2019

Investment Highlights

1

Clear mission

Commercialising a breakthrough implantable radiotherapy treatment for solid tumours

2

Sound science

Current and previous clinical studies demonstrate:

- **Excellent Local Disease Control**
 - **Prolonged Overall Survival**
 - **Encouraging resection rates**
 - **Superior outcomes to comparators**
 - **Excellent safety and tolerability profile**
-

3

Clear strategic path

- **\$2bn market opportunity** to improve standard of care in pancreatic cancer
- Targeting EU CE Mark for unresectable locally advanced pancreatic cancer
- **US Humanitarian Use Designation (HUD) for bile duct cancer granted**
- **Targeting US Humanitarian Device Exemption (HDE) for bile duct cancer**
- **Highly experienced management team**; strong clinical and commercial pedigree
- Manufacturing and logistics **optimised for supply of commercial quantities**
- At a potential value inflection point with multiple paths to commercialisation

Significant opportunity for OncoSil in pancreatic cancer

Current available treatment for pancreatic cancer

- Surgery (resection), if diagnosed early enough
- Chemotherapy (Gemcitabine & Abraxane, FOLFIRINOX)



- External radiation therapy

Issues with current standard of care

- Symptoms often unnoticed until cancer has metastasised; poor prognosis even with therapy:
 - Median survival ~8 months
 - 5 year survival less than 5%
- Surgery not feasible in 85% of patients
- Chemotherapeutic treatments limited effectiveness and are very toxic
- Radiation therapy is toxic to the patient's GI tract

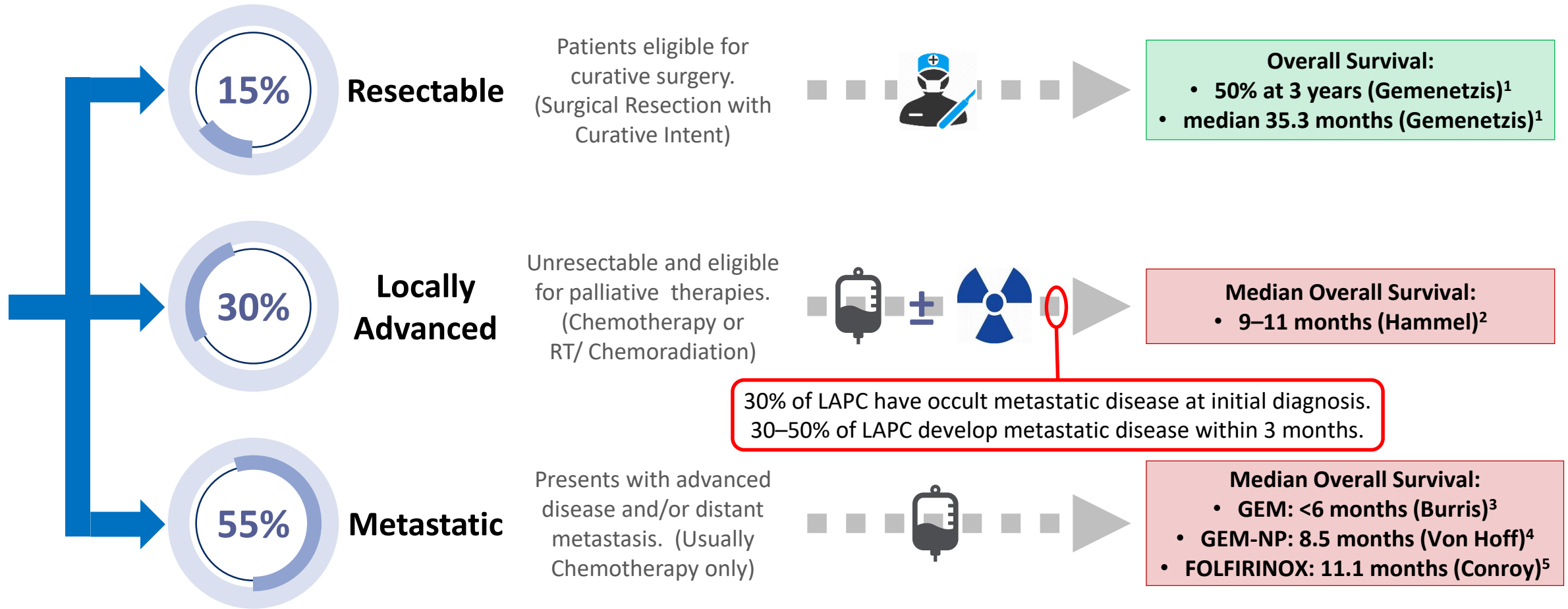
The Oncosil Opportunity

Only two drugs to have made significant improvements in pancreatic cancer in over 20 years:

- Gemcitabine approved over 21 years ago and Abraxane approved in 2013
- Median overall survival has increased by only 2 months (to 8.5 months) over the past 20 years

Significant opportunity for OncoSil to become standard of care in combination with Chemotherapy

Disease Prognosis & Treatment Options



¹ Gemenetzis, George et al. Survival in Locally Advanced Pancreatic Cancer After Neoadjuvant Therapy and Surgical Resection. *Annals of Surgery* 2019; 270: 340-347.

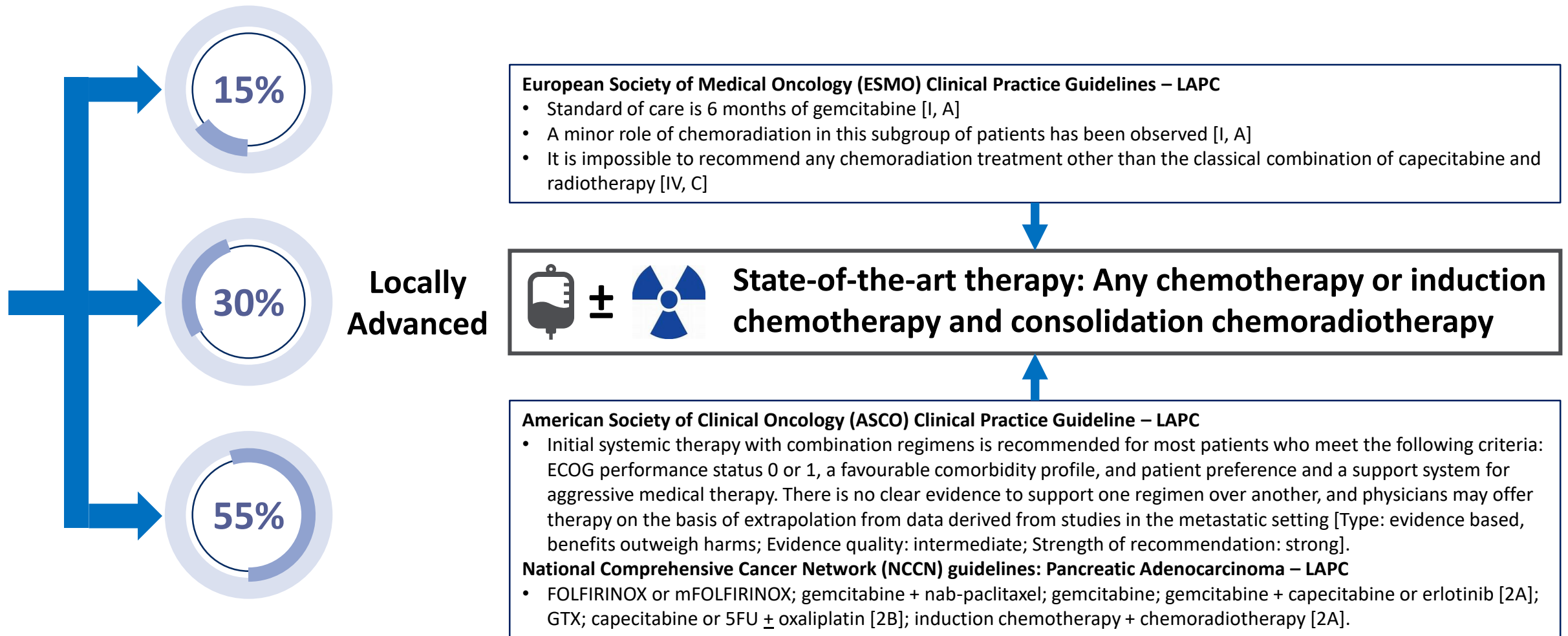
² Hammel, Pascal et al. Effect Of Chemoradiotherapy Vs Chemotherapy On Survival In Patients With Locally Advanced Pancreatic Cancer Controlled After 4 Months Of Gemcitabine With Or Without Erlotinib. *JAMA* 315.17 (2016): 1844.

³ Borris, Howard, A et al. Improvements in survival and clinical benefit with gemcitabine as first-line therapy for patients with advanced pancreas cancer: a randomized trial. *Journal Clinical Oncology*. 1997 Jun;15(6):2403-13

⁴ Von Hoff, Daniel D. et al. Increased Survival In Pancreatic Cancer With Nab-Paclitaxel Plus Gemcitabine. *New England Journal of Medicine* 369.18 (2013): 1691-1703.

⁵ Conroy, Thierry et al. FOLFIRINOX Versus Gemcitabine For Metastatic Pancreatic Cancer. *New England Journal of Medicine* 364.19 (2011): 1817-1825.

Disease Prognosis & Treatment Options





Target markets

Annual incidence

Global opportunity

Pancreatic cancer US>\$2.0bn

Liver cancer US\$1.4bn



1. GLOBOCAN 2012: Estimated Cancer Incidence Worldwide in 2012 (IARC/WHO). Accessed 22 Apr 2016, from http://globocan.iarc.fr/Pages/fact_sheets_population.aspx

2. Datamonitor Healthcare 2013

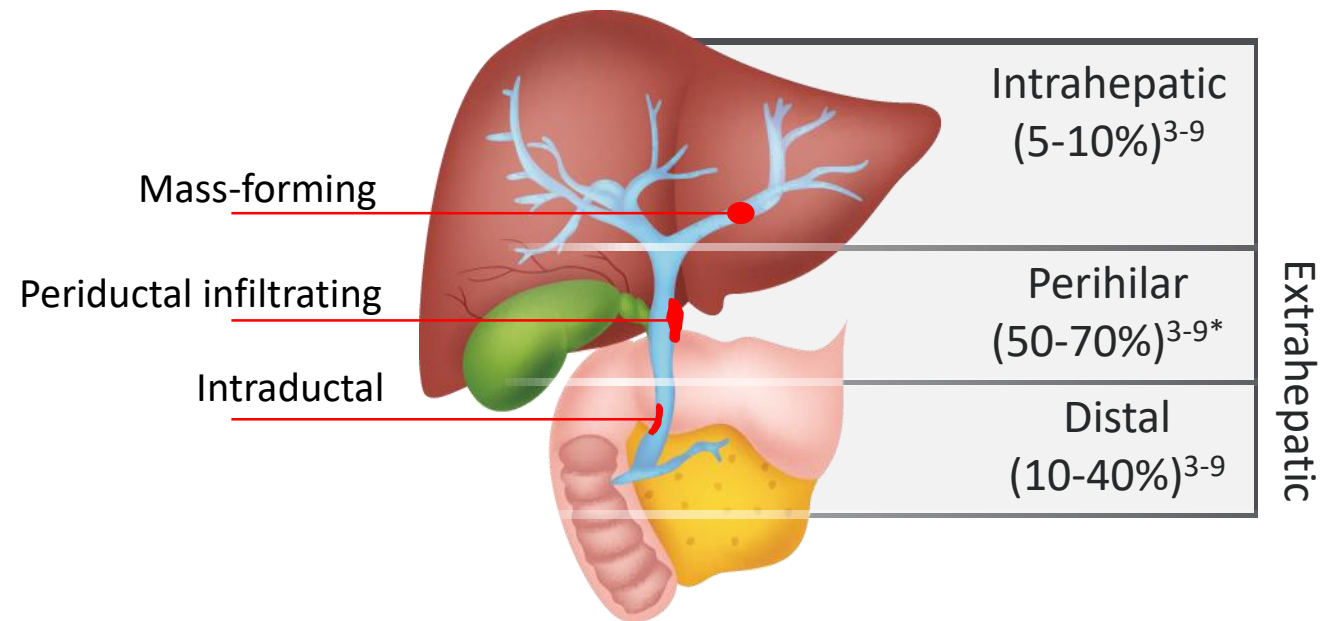
3. OncoSil dose pricing, \$USD 25,000

Classification of Cholangiocarcinoma (bile duct cancer)

CCA can be classified as intrahepatic (ICC), perihilar (pCCA) or distal (dCCA). pCCA and dCCA can be grouped as extrahepatic cholangiocarcinoma (ECC)

Morphological classification^{1,2}

Morphology	Description
Mass-forming	<ul style="list-style-type: none"> Homogeneous mass with irregular but well-defined margins Majority of ICC are mass-forming
Periductal infiltrating	<ul style="list-style-type: none"> Elongated or branch-like growth invading dilated, diffusely narrowed/obliterated bile ducts No mass formation Majority of pCCA are periductal infiltrating Unlikely to be suitable for OncoSil™
Intraductal	<ul style="list-style-type: none"> Small, sessile or polypoid papillary adenocarcinomas spread superficially along mucosa of dilated bile duct



Adapted from European Network for the Study of Cholangiocarcinoma <http://conf2016.enscca.org/scientific-information/the-disease-of-cholangiocarcinoma/> [Accessed July 2018]

* Clinical expert opinion confirms pCCA comprises 50% of all ECC tumours

- Chung YE *et al* (2009) *Radiographics* 29: 683-700
- Lim JH (2003) *AJR AM J Roentgenol* 181:819-829
- Razumilava N *et al* (2014) *Lancet* 383(9935): 2168-2179
- Yazici C *et al* (2014) *Expert Rev Gastroenterol Hepatol* 8(1): 63-82
- DeOliveira ML *et al* (2007) *Annals Surg* 245(5): 755-762

- Zhang W and Yan LN (2014) *World J Gastrointest Pathophysiol* 5(3): 344-354
- Rizvi S and Gores GJ (2014) *Digestion* 89(3): 216-224
- Nakeeb A *et al* (1996) *Annals Surg* 224(4): 463-473
- Hong JC *et al* (2011) *Arch Surg* 146(6): 683-689

OncoSil™ In Cholangiocarcinoma

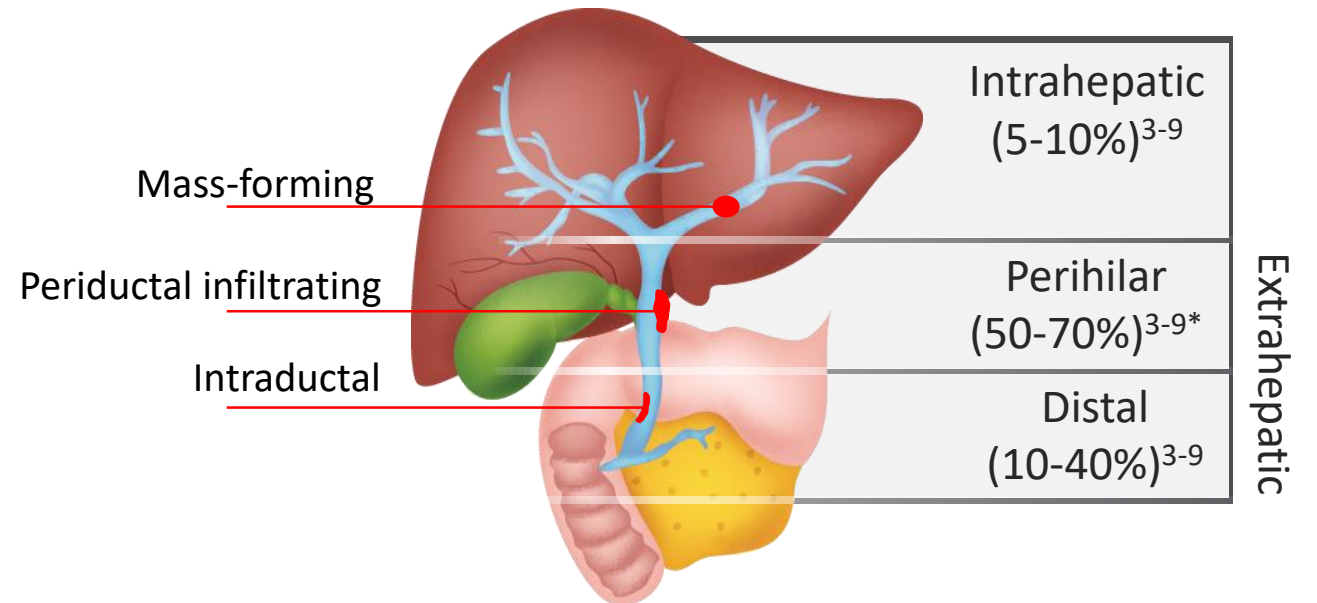


Intrahepatic and Distal CCA

Patients with Intrahepatic and Distal CCA

would be eligible for OncoSil™. These variants of CCA can be accessed, either percutaneously under CT guidance and/or via endoscopic ultrasonography. The OncoSil™ device has demonstrated that it can be safely and feasibly implanted into tumors using both these implantation techniques.

The dose of OncoSil™ requires an accurate evaluation of the volume of the tumor to be injected and as these CCA variants are mass forming tumors they are amenable to OncoSil™ implantation.



Adapted from European Network for the Study of Cholangiocarcinoma <http://conf2016.enscca.org/scientific-information/the-disease-of-cholangiocarcinoma/> [Accessed July 2018]

* Clinical expert opinion confirms pCCA comprises 50% of all ECC tumours

A photograph of surgeons in an operating room, wearing blue scrubs, masks, and caps, illuminated by blue surgical lights. The scene is focused on the surgeons' hands and faces as they work.

1 The OncoSil™ Device

Device Overview



Radioactive Microparticles that contain a pure beta emitting isotope (^{32}P).

Microparticles are suspended in Diluent to allow direct injection into the tumour.

Microparticles are implanted directly into a tumour via EUS, and are designed to deliver an absorbed dose of 100Gy.

Single use device and remains in the tumor permanently following implantation.

In therapeutic use 98% of the radiation is delivered within 81 days.

OncoSil™ is classified as an Active Implantable Medical Device (AIMD) and meets the requirements of a sealed source.

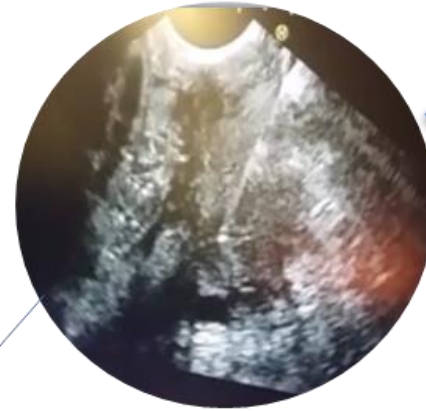
Device Procedure



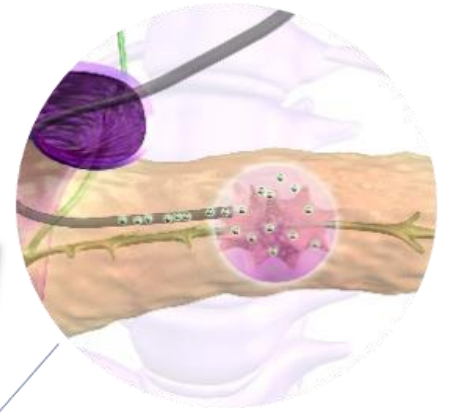
OncoSil™
Microparticles are
suspended in a
rheological Diluent



Endoscope
guided
(ultrasound) into
the upper
intestine



Using ultrasound
imaging the needle is
guided into the
target lesion



OncoSil™ injected
directly into the tumor.
Implanted Microparticle
localization shown on
Bremsstrahlung imaging

Manufacturing & Supply Chain



Management Expertise

In-house expertise
– over 20 years with nuclear medicine products

ISO certified process using **outsourced GMP** manufacturers



Manufacturing capacity to meet needs

Ultra Pure Base Material supply secured

Intermediate products can be stored for lengthy periods

Current Inventory is sufficient to meet clinical study commencement and early commercial needs



Supply chain in place and validated

DG handling & distribution by **partner, Eckert & Ziegler** (Germany)

100 doses shipped for clinical studies over an 18 month period

4 x Nuclear Reactors verified for OncoSil™ (including OPAL)



Logistics of Dangerous Goods

Logistics for all radioactive goods shipments have been verified.

Commercial quantities can be shipped

All major markets: USA, UK, Australia, EU and parts of Asia

OncoSil™ System is shipped in a **registered Type A package**

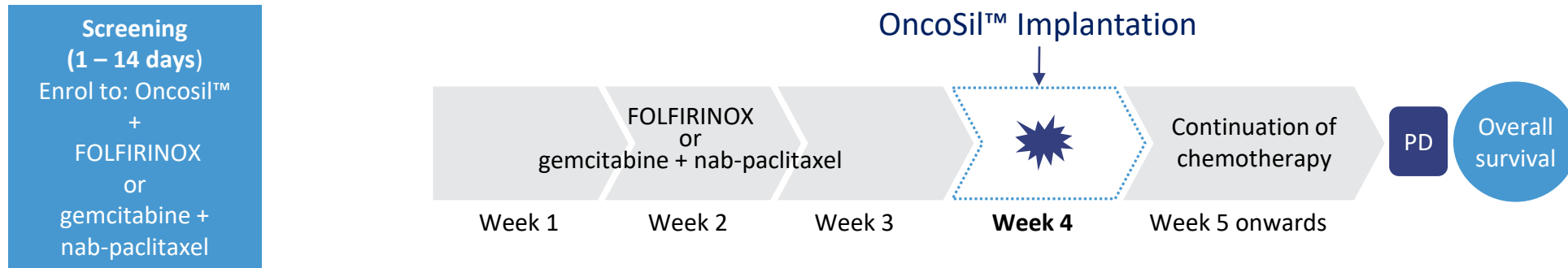


PanCO Study

Results & Naïve Indirect Treatment Analysis



PanCO Study Design and Objective



- 8 weekly CT – RECIST 1.1 and tumour volume (independent central reader analysis)
- SPECT-CT Bremsstrahlung imaging – Days 1 and 7
- Blood and urine P-32 analysis
- FDG-PET – Baseline and Week 12
- CA 19-9 tumour marker serial analysis
- Chemotherapy by physician choice

- The primary objective of PanCO was to assess the **safety** of the device and determine **the feasibility of the administration** approach in the setting of advanced, unresectable pancreatic cancer.
 - Primary efficacy measure was LDCR_{16 weeks}

PanCO Patient Population And Study Criteria

Key eligibility criteria

- Histologically or cytologically proven adenocarcinoma of the pancreas
 - Unresectable locally advanced pancreatic carcinoma
 - Target tumour diameter 2–6 cm
 - ECOG Performance Status 0 to 1
 - No distant metastases
 - No prior radiotherapy or chemotherapy for pancreatic cancer
-

Primary endpoint

- Safety and tolerability
-

Secondary endpoints: Efficacy

- Local Disease Control Rate (LDCR) at 16 weeks
 - Overall Survival (OS)
 - Local Progression-Free Survival (LPFS), within the pancreas
 - Progression-Free Survival (PFS), all sites
-

Exploratory Assessment

- Target Tumour Volumetric (TV) Change
- Target Tumour FDG-PET Response

PanCO Study: Results and Comparator Analysis



- LDCR_{16 weeks} met primary endpoint** – Local Disease Control Rates at 16 weeks (LDCR_{16 weeks}) of **82% in the Intention-to-Treat (ITT) (p=0.0001)** cohort of enrolled patients and **90.5% in the Per Protocol (PP) (p<0.0001)** population that received OncoSil™ plus CT, demonstrate that the PanCO study convincingly met its *a priori* primary performance endpoint. **This convincingly demonstrates that OncoSil™ plus CT is better than CT alone.**
- Prolonged OS** – Prolonged median overall survival of 15.5 months in the ITT cohort and **16.0 months in the PP population**, with one-year survival rates of 63.4% and 64.0%, respectively. In the naïve indirect treatment comparison, these were significantly longer ($p<0.001$) than CT-only and ICT + CCRT regimens, representing a **clinically relevant 20% reduction in the risk of death compared to CT-only and ICT + CCRT studies.**
- Encouraging resection rate** – Encouraging rate of surgical resection with curative intent in **nearly one-in-four PanCO patients (23.8%)** that received OncoSil™ plus CT, translating to 20.0% in the ITT cohort, which were significantly greater than rates reported in the CT-only and ICT + CCRT studies ($p<0.001$). Notably, the R0 (Tumour Free) margin status rate in PanCO was 80%. Surgical resection of pancreatic cancer, particularly in patients previously determined to be unresectable, profoundly **improves patients' prognosis from a five-year survival rate of 5% to greater than 20%.**
- Prolonged PFS** – Progression-free survival (PFS) was also prolonged (9.3 months in both ITT and PP cohorts), and was significantly greater than the “state-of-the-art” CT-only and ICT + CCRT studies ($p<0.001$)
- Higher DCR & ORR** – Disease control and overall response rates in the PanCO study – 95.7% and 29.8%, respectively, in the ITT group; **100% and 31.0% in the PP population** – underline the response following OncoSil™ administration and were again **significantly greater than the CT-only and ICT + CCRT studies in the naïve indirect treatment comparison.**

PanCO Study: Results and Comparator Analysis (2/2)



-
- Low chemo intensity** — These encouraging results were achieved despite relatively low chemotherapy intensity due to poor tolerability to the chemotherapy agents, and consequently dose delays \geq one week, dose reductions and/or termination of CT were seen in patients prior to OncoSil™ administration, as well as in a similar proportion of the patients who did not receive OncoSil™.
 - Superior outcomes to comparators** — The naïve indirect treatment comparison confirms that the PanCO study results were consistently and statistically significantly better than the results from CT-only and ICT + CCRT studies, and clearly demonstrates that OncoSil™ plus CT provides clinically relevant benefits for patients with unresectable LAPC that are superior to those reported with CT alone.
 - Safety Analysis** — Satisfactory safety profile with no evidence of significant safety concerns or unexpected/serious toxicities associated with the OncoSil™ device. No evidence to suggest any significant additional risk associated with OncoSil™ treatment over that expected with CT alone.

Median Overall Survival Results: PanCO vs. Naïve Indirect Treatment Comparison

Median overall survival

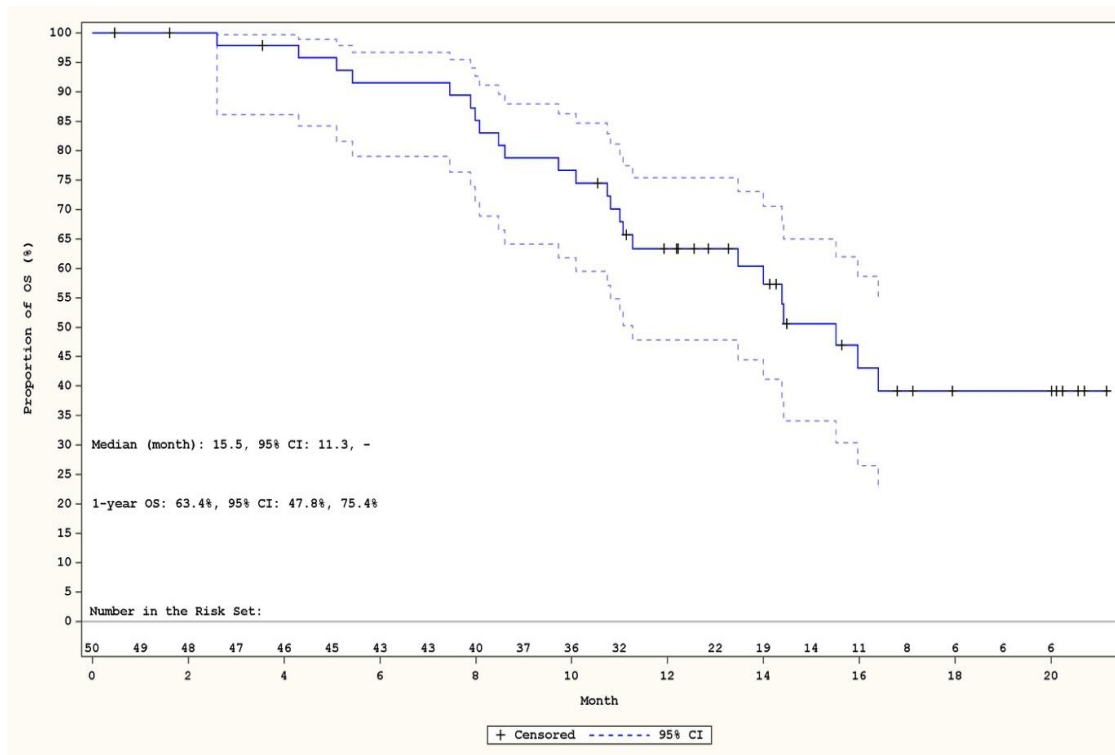
OS remains the gold-standard outcome for benchmarking the clinical benefit in patients with pancreatic cancer, as it does for many other cancers

PanCO Overall Survival (OS)

at a Median Follow-Up of 16.1 Months

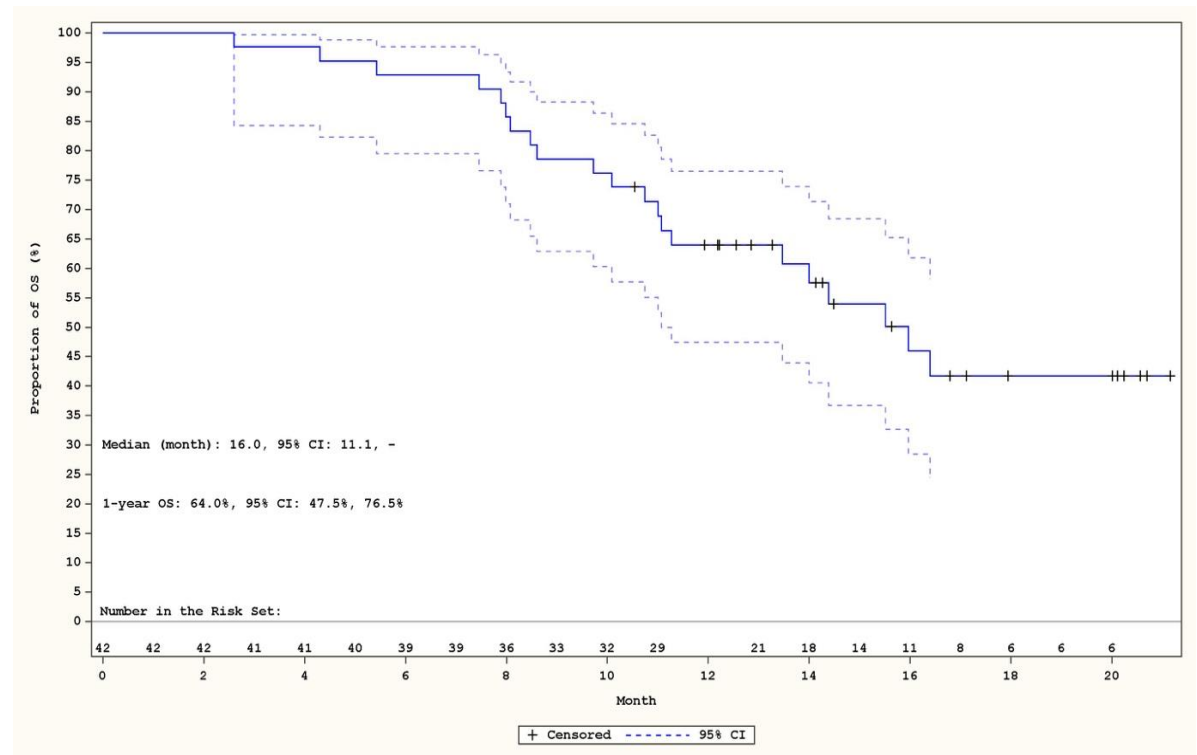
PanCO ITT cohort

- Median OS: 15.5 months (95% CI: 11.3, nc)
- 1-year survival: 63.4% (95% CI: 47.8%, 75.4%)

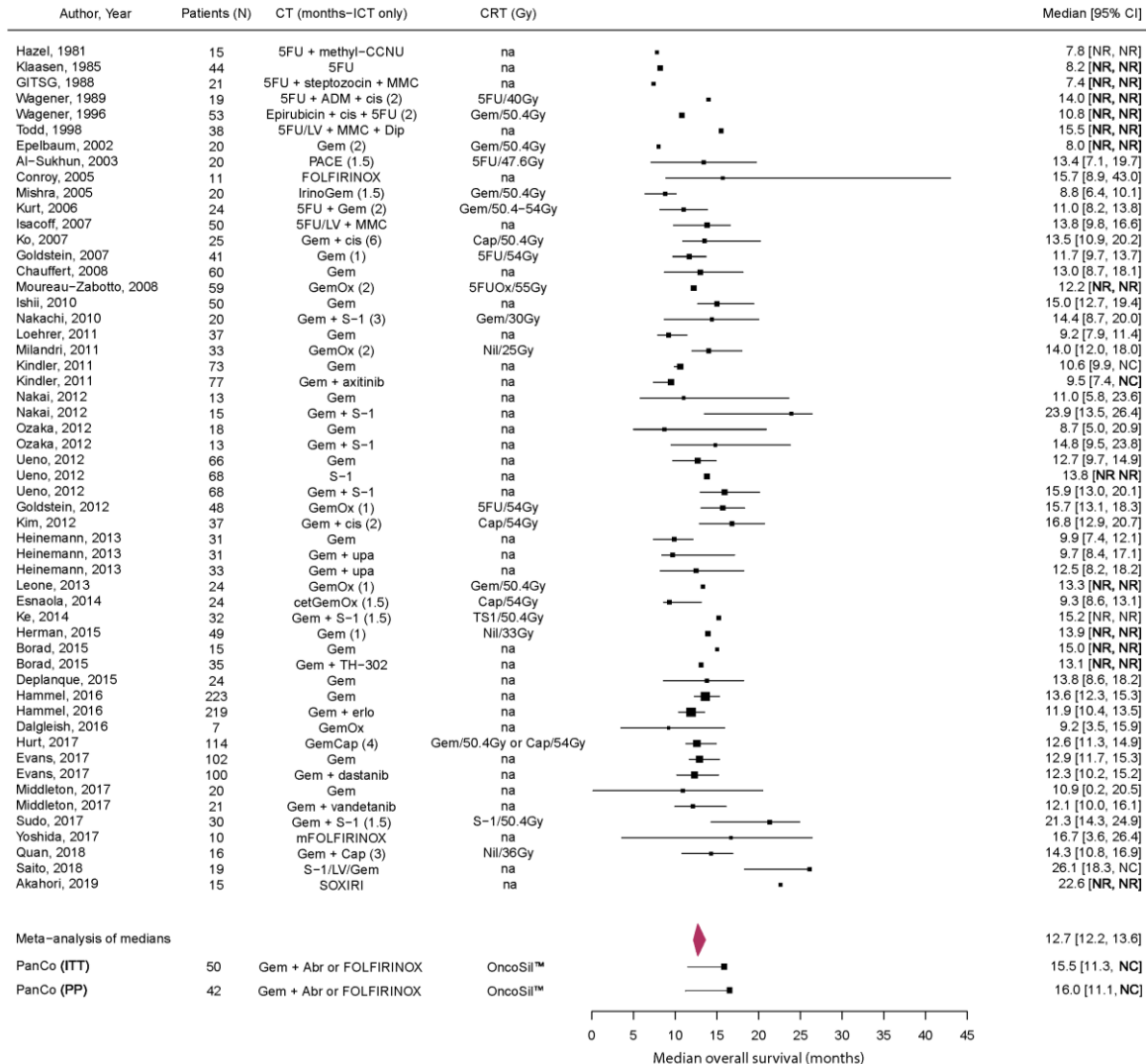


PanCO PP cohort

- Median OS: 16.0 months (95% CI: 11.1, nc)
- 1-year survival: 64.0% (95% CI: 47.5%, 76.5%)



Systematic Literature Review: Overall Survival Analyses (All Identified Treatment Arms)



Abbreviations: 5FU, Fluorouracil; ADM, Adriamycin (doxorubicin); Abr, abraxane (nab-paclitaxel); Cap, capecitabine; CCRT, induction chemotherapy with consolidation chemoradiotherapy; cet, cetuximab; C.I., confidence interval; cis, cisplatin; CRT, chemoradiotherapy; CT, chemotherapy; Dip, docetaxel/ifosfamide/cisplatin; erlo, erlotinib; FOLFIRINOX, leucovorin/fluorouracil/irinotecan/oxaliplatin; Gem, gemcitabine; ICT, induction chemotherapy; irino, irinotecan; ITT, intention-to-treat; LV, leucovorin; MMC, mitomycin C; na, not applicable; NC, not calculable (for PanCO study upper bound C.I. not yet reached); NR, not reported; Ox, oxaliplatin; PACE, cisplatin/doxorubicin/cyclophosphamide/etoposide; PP, per protocol; SOXIRI, S-1/oxaliplatin/irinotecan; upa, urokinase type plasminogen activator

Summary of Analysis

Regimen	Median OS	(95% CI)
CT-only and ICT + CCRT	12.7 months	(12.2, 13.6)
PanCO (ITT)	15.5 months	(11.3, NC)
PanCO (PP)	16.0 months	(11.1, NC)

Abbreviations: C.I., confidence interval; ITT, intention-to-treat (enrolled participants); nc, non-calculable; PP, per protocol (enrolled and implanted participants); OS, overall survival.

Overall Survival Summary of the Evidence on Clinical Benefit Meta-Analysis of Medians: PanCO Against ‘State-of-the-Art’ Therapies

	Median OS (months; 95% C.I.)
PanCO (ITT)	15.5 (11.3, NC)
PanCO (PP)	16.0 (11.1, NC)
All Treatments	12.7 (12.2, 13.6)
CT Only	12.7 (11.9, 13.6)
CCRT Only	12.6 (12.2, 14.0)

Overall Survival: Statistical Comparison of Median OS, from PanCO Against ‘State-of-the-Art’ Therapies

Parameter of Interest	CT Type	ITT/PP	PanCO Median	N Trials	n>PanCO	p-value
OS	CT + ICT + CCRT	ITT	15.5	54	10	<0.001
	CT + ICT + CCRT	PP	16.0	54	6	<0.001
	CT only	ITT	15.5	34	7	<0.001
	CT only	PP	16.0	34	4	<0.001
	ICT + CCRT	ITT	15.5	20	3	0.001
	ICT + CCRT	PP	16.0	20	2	<0.001

Secondary Outcome Results: PanCO vs. Naïve Indirect Treatment Comparison

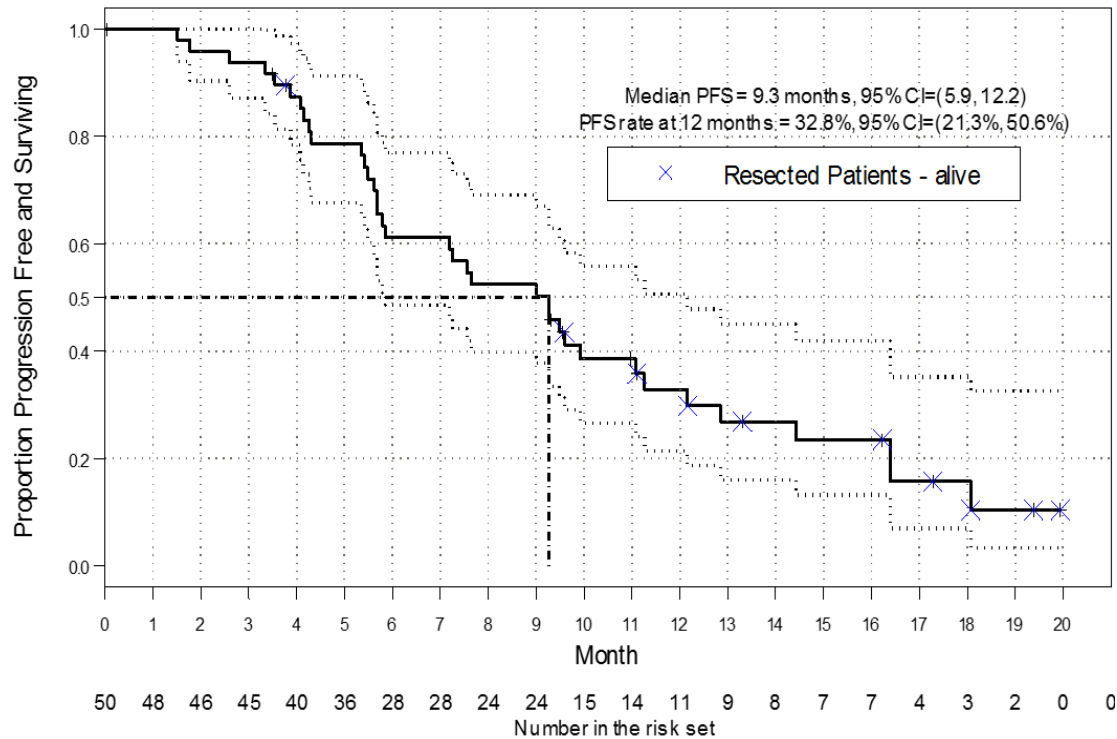
Median PFS, LPFS (PanCO only), one-year survival, LDCR (PanCO only), DCR, ORR and resection rate

PanCO Progression-Free Survival (PFS)

at a Median Follow-Up of 16.1 Months

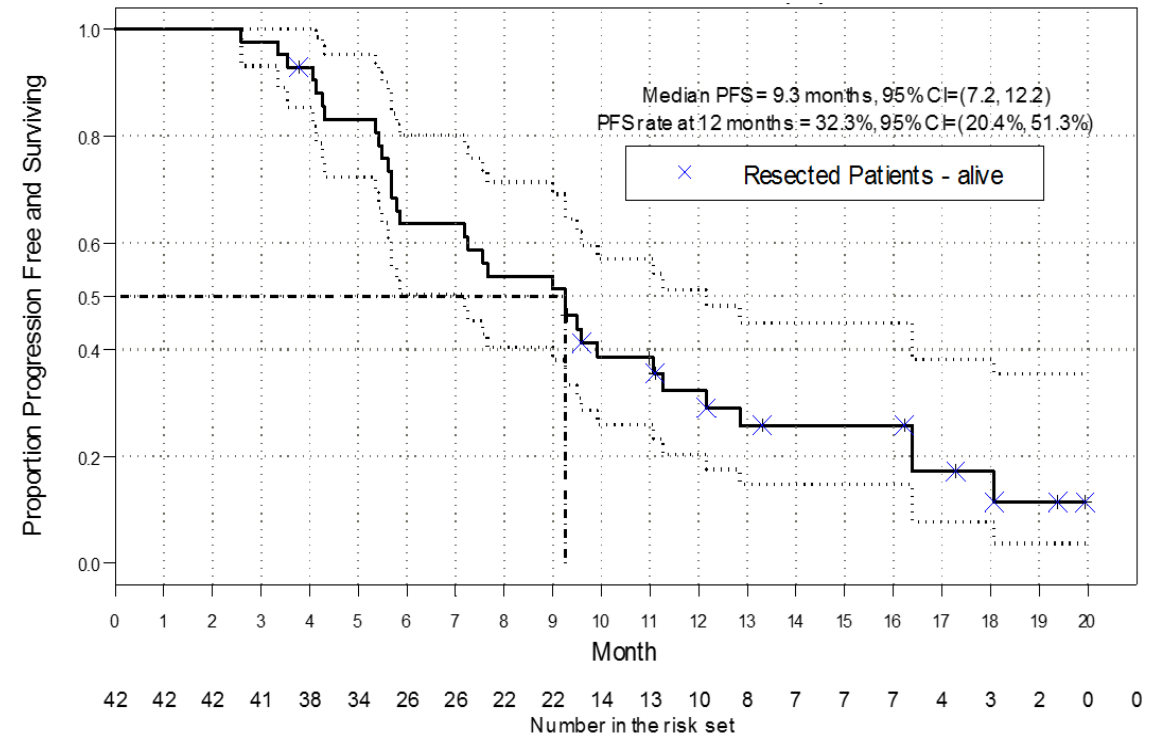
PanCO ITT cohort

- Median PFS: 9.3 months (95% CI: 5.9, 12.2)
- 1-year survival: 32.8% (95% CI: 21.3%, 50.6%)

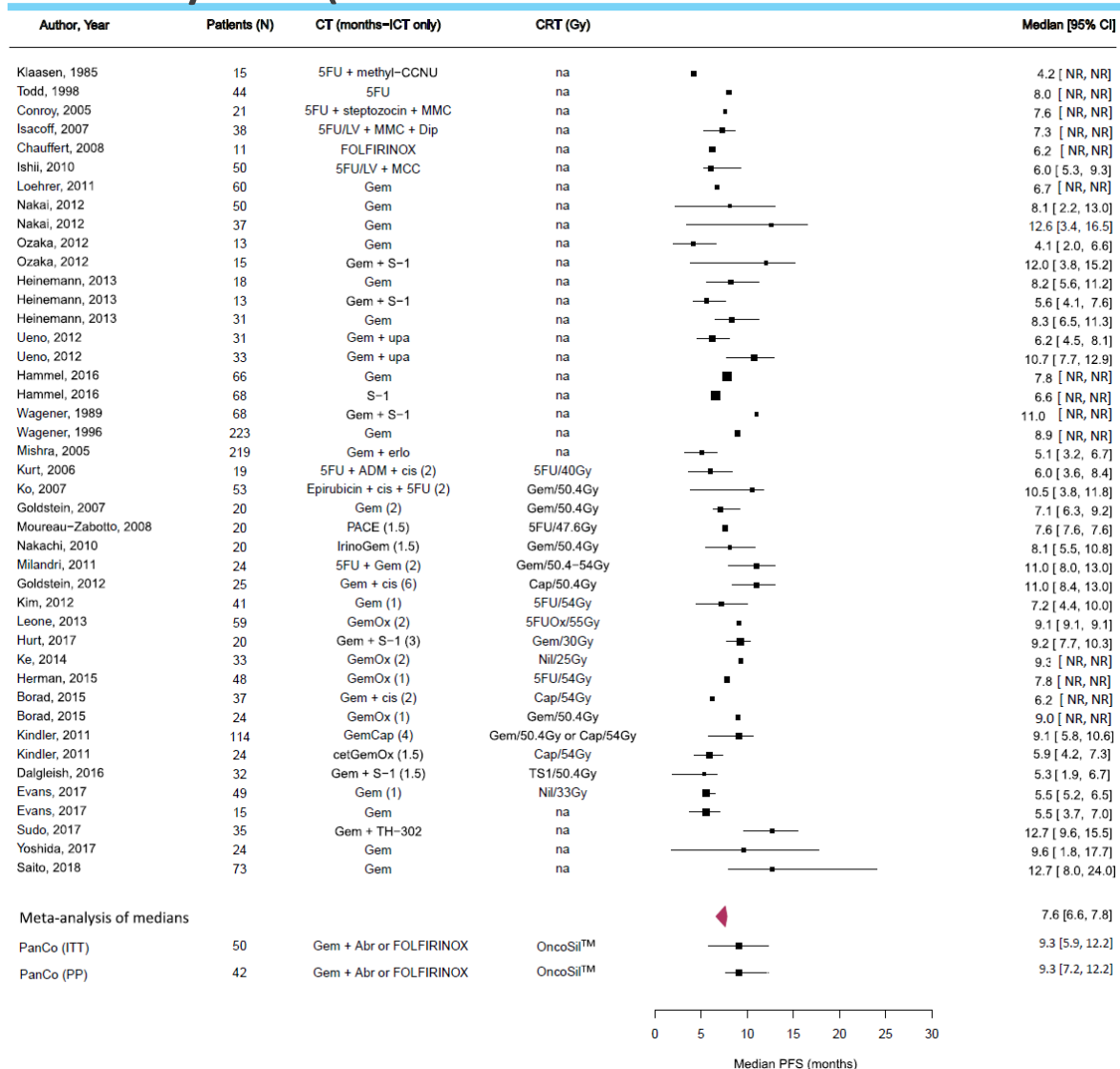


PanCO PP cohort

- Median PFS: 9.3 months (95% CI: 7.2, 12.2)
- 1-year survival: 32.3% (95% CI: 20.4%, 51.3%)



Systematic Literature Review: Progression-Free Survival Analyses (All Identified Treatment Arms)



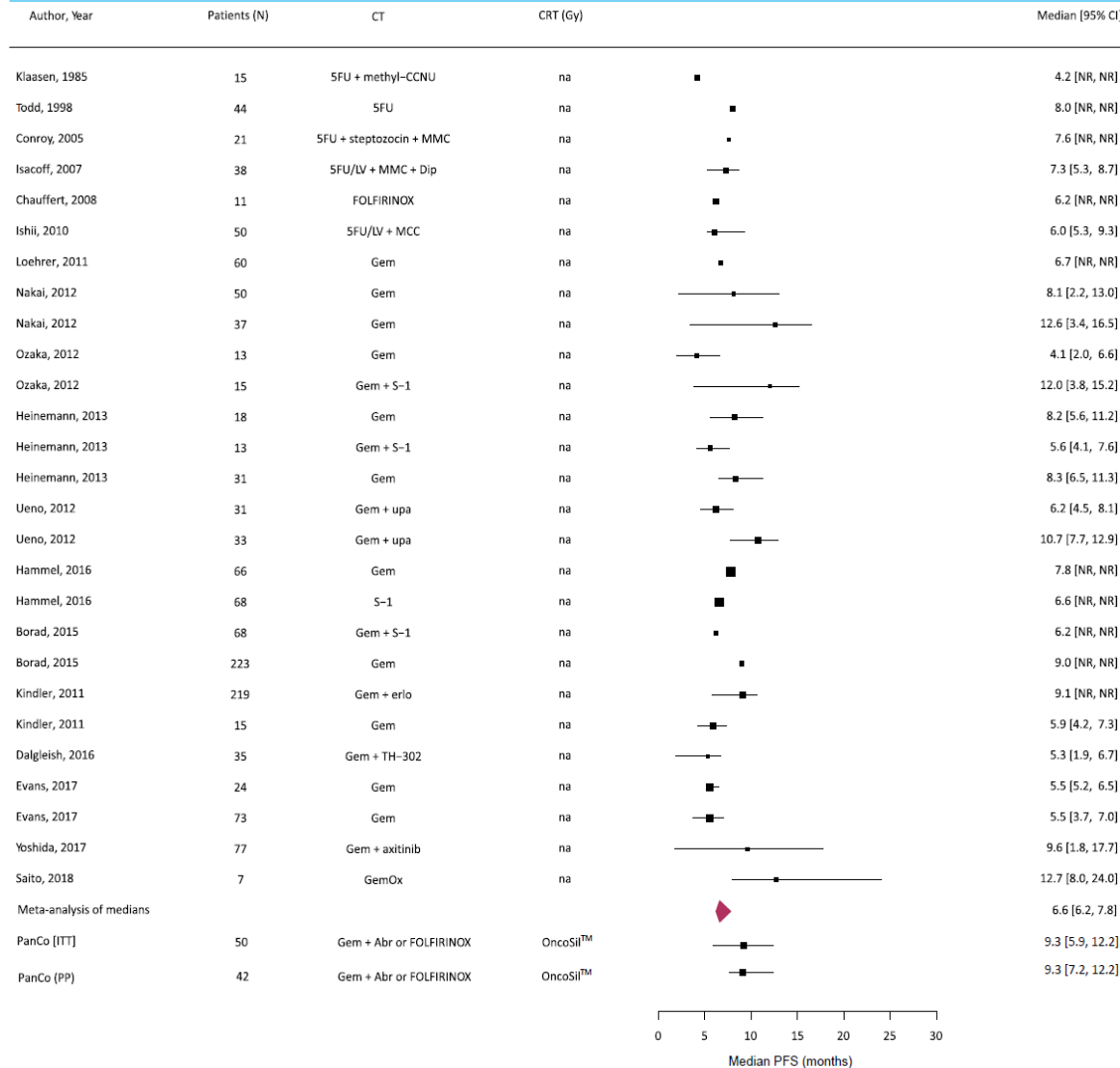
Abbreviations: 5FU, Fluorouracil; ADM, Adriamycin (doxorubicin); Abr, abraxane (nab-paclitaxel); Cap, capecitabine; CCRT, induction chemotherapy with consolidation chemoradiotherapy; cet, cetuximab; C.I., confidence interval; cis, cisplatin; CT, chemotherapy; Dip, docetaxel/ifosfamide/cisplatin; erlo, erlotinib; FOLFIRINOX, leucovorin/fluorouracil/irinotecan/oxaliplatin; Gem, gemcitabine; ICT, induction chemotherapy; irino, irinotecan; ITT, intention-to-treat; LV, leucovorin; MMC, mitomycin C; na, not applicable; NR, not reported; Ox, oxaliplatin; PACE, cisplatin/doxorubicin/cyclophosphamide/etoposide; PFS, progression-free survival; PP, per protocol; SOXIRI, S-1/oxaliplatin/irinotecan

Summary of Analysis

Regimen	Median PFS	(95% CI)
CT-only and ICT + CCRT	7.6 months	(6.6, 7.8)
PanCO (ITT)	9.3 months	(5.9, 12.2)
PanCO (PP)	9.3 months	(7.2, 12.2)

Abbreviations: C.I., confidence interval; ITT, intention-to-treat (enrolled participants); PP, per protocol (enrolled and implanted participants); PFS, progression-free survival.

Systematic Literature Review: Progression-Free Survival Analyses (CT Treatment Arms Only)



Abbreviations: 5FU, Fluorouracil; ADM, Adriamycin (doxorubicin); Abr, abraxane (nab-paclitaxel); Cap, capecitabine; CCRT, induction chemotherapy with consolidation chemoradiotherapy; cet, cetuximab; C.I., confidence interval; cis, cisplatin; CT, chemotherapy; Dip, docetaxel/ifosfamide/cisplatin; erlo, erlotinib; FOLFIRINOX, leucovorin/fluorouracil/irinotecan/oxaliplatin; Gem, gemcitabine; ICT, induction chemotherapy; irino, irinotecan; ITT, intention-to-treat; LV, leucovorin; MMC, mitomycin C; na, not applicable; NC, not calculable (for PanCO study upper bound C.I. not yet reached); NR, not reported; Ox, oxaliplatin; PACE, cisplatin/doxorubicin/cyclophosphamide/etoposide; PFS, progression-free survival; PP, per protocol; SOXIRI, S-1/oxaliplatin/irinotecan

Summary of Analysis

Regimen	Median PFS	(95% CI)
CT-only	6.6 months	(6.2, 7.8)
PanCO (ITT)	9.3 months	(5.9, 12.2)
PanCO (PP)	9.3 months	(7.2, 12.2)

Abbreviations: C.I., confidence interval; ITT, intention-to-treat (enrolled participants); PP, per protocol (enrolled and implanted participants); PFS, progression-free survival.

PanCO Local Disease Control Rate at 16 weeks (LCDR_{16 weeks})

⚙️ PanCO Local Disease Control Rate at 16 weeks (LCDR_{16 weeks}) per RECIST 1.1

	ITT (N=50)	PP (N=42)
Number of study participants with local disease control at Week 16	41	38
LCDR _{16 weeks} (95% CI)	82.0% (68.6% ,91.4%)	90.5% (77.4%, 97.3%)
<i>p</i> -value	0.0013	<=0.0001

⚙️ Maintenance of local tumour control: Week 24 LCDR

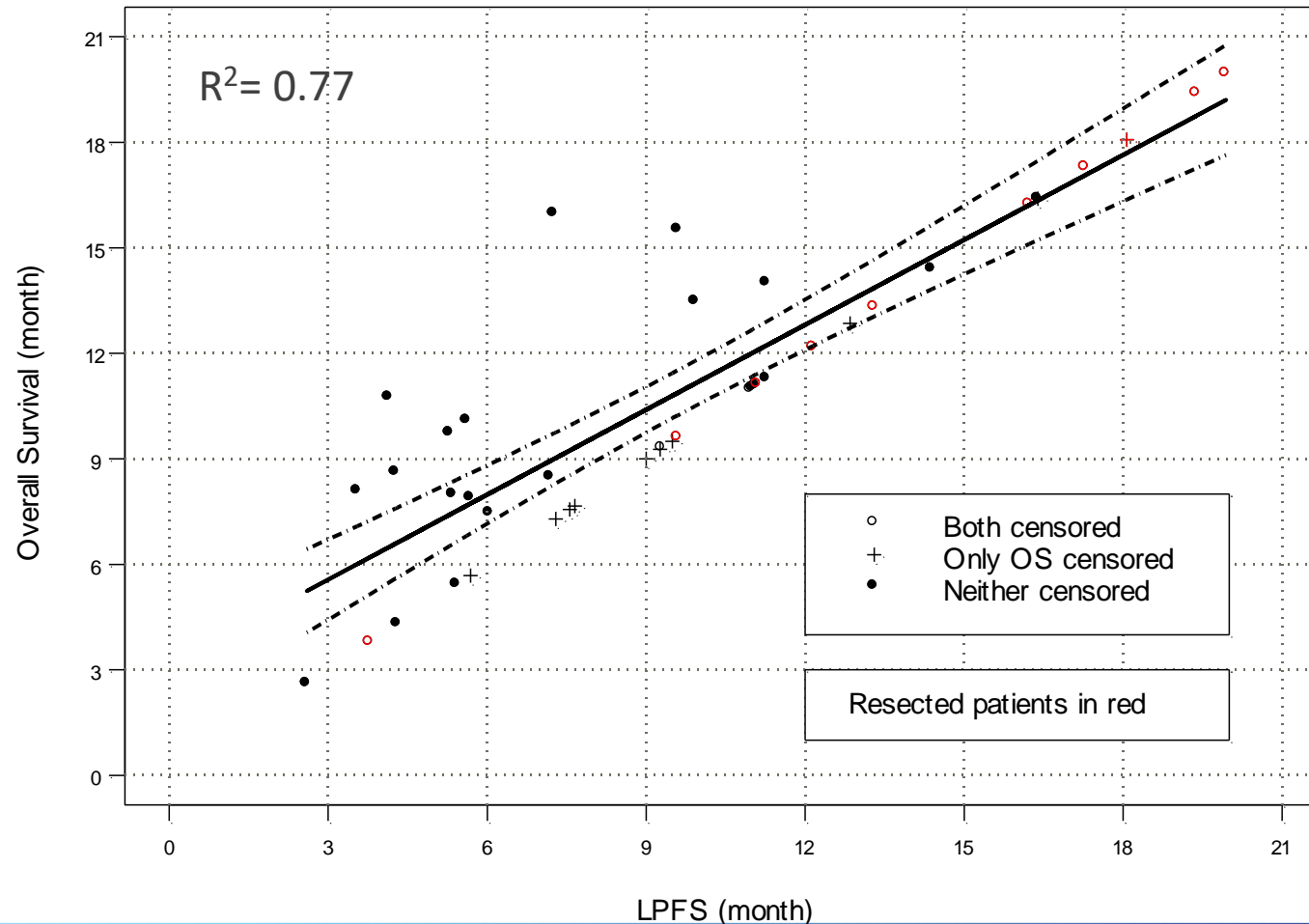


30/42 implanted study participants had SD, PR or had undergone surgical resection with curative intent at Week 24:

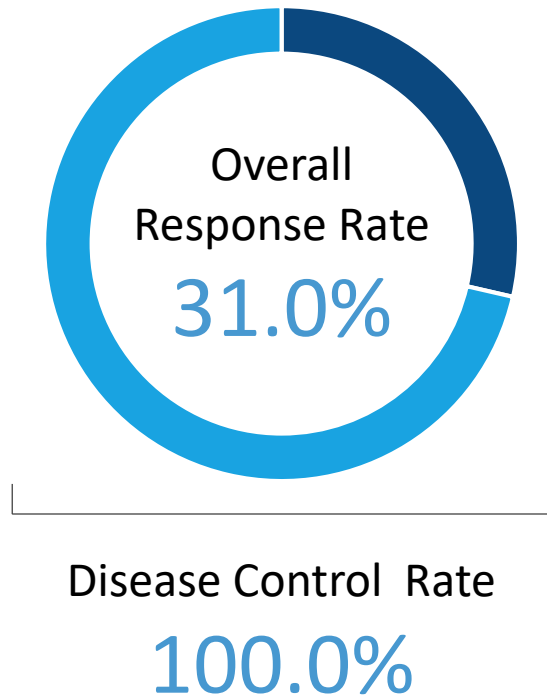
LDCR_{24 weeks} = 71.4% (95% CI: 55.4%, 84.3%)

PanCO Local Progression Free Survival and Overall Survival Correlation – Line of Best Fit 95% CI

Scatter Plot of Overall Survival Vs Local PFS
Line of Best Fit 95% CI



PanCO Best Response Per RECIST 1.1



Overall Response Rate (ORR)

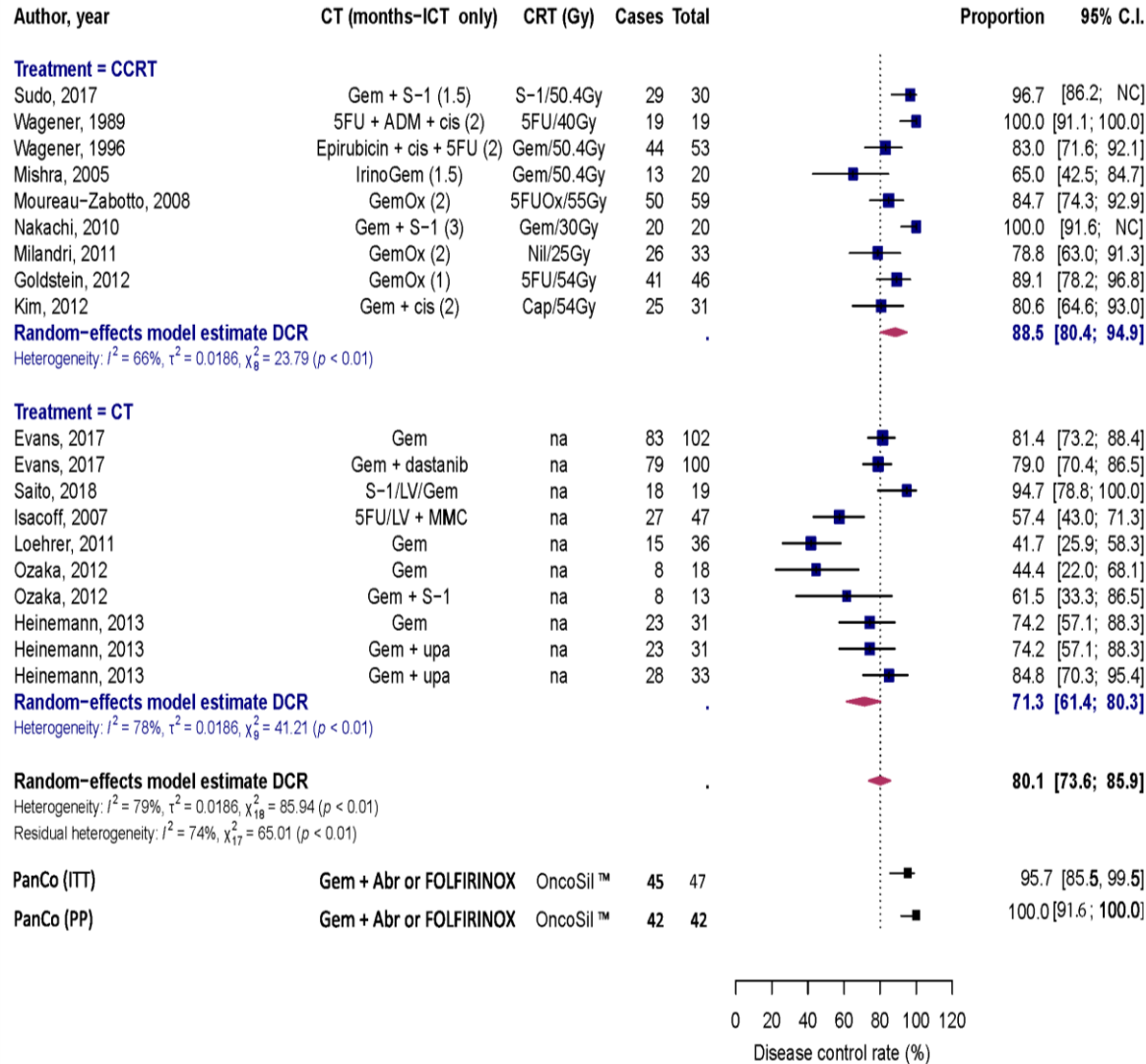
- 13 implanted study participants (31.0%; 95% CI: 17.6%, 47.1%) achieved a Best Response of Partial Response (PR) based on RECIST 1.1 assessment.
 - Defined as a $\geq 30\%$ decrease in the longest diameter of the local target tumour (compared to baseline), without the appearance of one or more new lesions.

Disease Control Rate (DCR)

- All 42 implanted study participants (100.0%; 95% CI: 91.6%, 100.0%) achieved a Best Response of Stable Disease (SD) or better based on RECIST 1.1 assessment.
 - Defined as a $\leq 20\%$ increase in the longest diameter of the local target tumour (compared to baseline), without the appearance of one or more new lesions.

Systematic Literature Review: Disease Control Rate

Analyses Subgroups Based On Treatment



Abbreviations: 5FU, Fluorouracil; ADM, Adriamycin (doxorubicin); Abr, abraxane (nab-paclitaxel); Cap, capecitabine; CRT, consolidation chemoradiotherapy; C.I., confidence interval; cis, cisplatin; CT, chemotherapy; DCR, disease control rate; FOLFIRINOX, leucovorin/fluorouracil/irinotecan/oxaliplatin; Gem, gemcitabine; ICT, induction chemotherapy; irino, irinotecan; ITT, intention-to-treat; LV, leucovorin; MMC, mitomycin C; na, not applicable; NC, not calculable (for PanCO study upper bound C.I. not yet reached); Ox, oxaliplatin; PP, per protocol

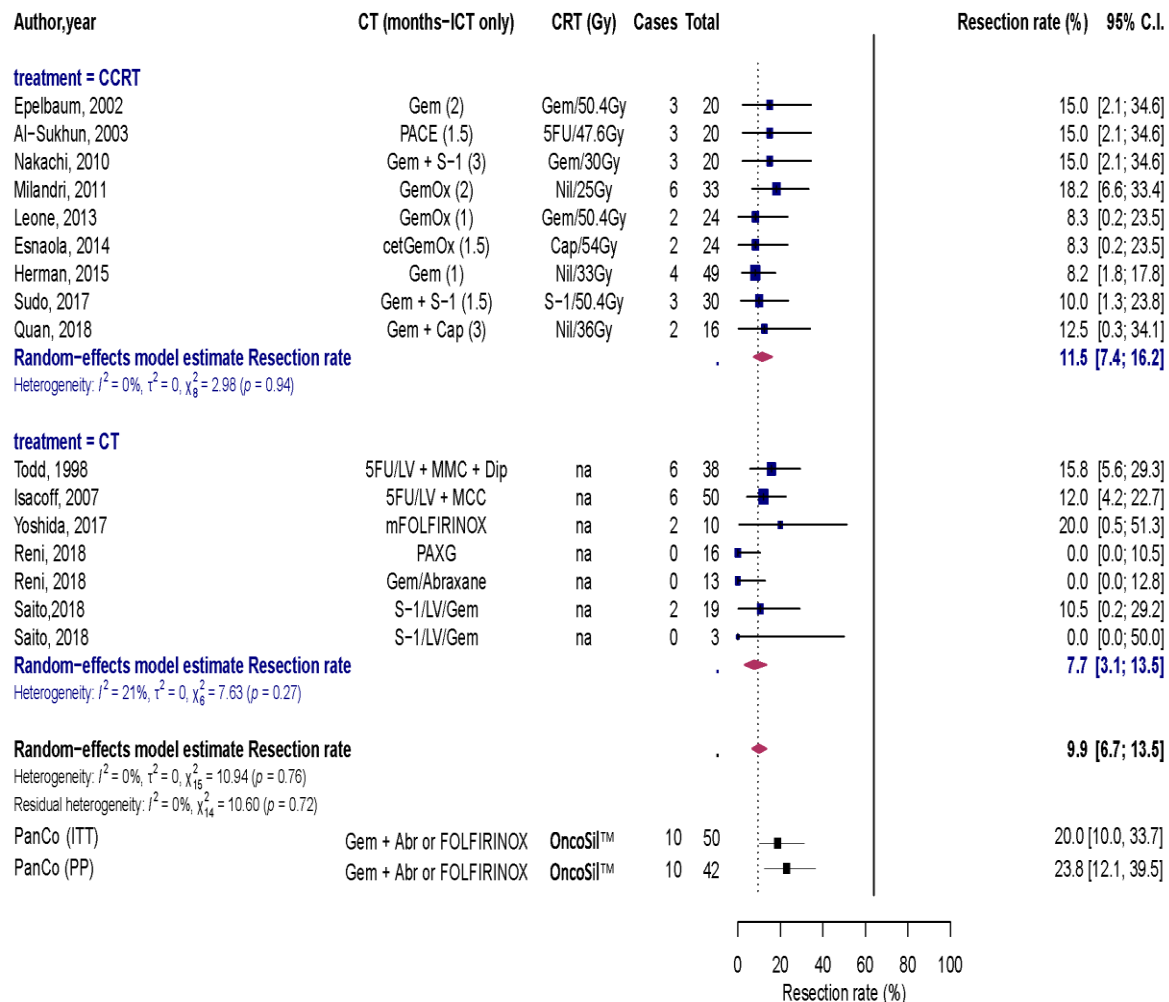
Summary of Analysis

Regimen	DCR	(95% CI)
CT-only and ICT + CCRT	80.1%	(72.9, 86.4)
CT-only	71.3%	(73.6, 85.9)
ICT + CCRT	88.5%	(80.4, 94.9)
PanCO (ITT)	95.7%	(85.5, 99.5)
PanCO (PP)	100.0%	(91.6, 100)

Abbreviations: C.I., confidence interval; ITT, intention-to-treat (enrolled participants); PP, per protocol (enrolled and implanted participants); DCR, disease control rate.

Systematic Literature Review: Resection Rate Analyses

Subgroups Based On Treatment



Abbreviations: 5FU, Fluorouracil; Abr, abraxane (nab-paclitaxel); Cap, capecitabine; CRT, consolidation chemoradiotherapy; C.I., confidence interval; CT, chemotherapy; Dip, docetaxel/ifosfamide/cisplatin; FOLFIRINOX, leucovorin/fluorouracil/irinotecan/oxaliplatin; Gem, gemcitabine; ICT, induction chemotherapy; ITT, intention-to-treat; LV, leucovorin; MMC, mitomycin C; na, not applicable; Ox, oxaliplatin; PACE, cisplatin/doxorubicin/cyclophosphamide/etoposide; PAXG, nab-paclitaxel/gemcitabine/capecitabine/cisplatin; PP, per protocol

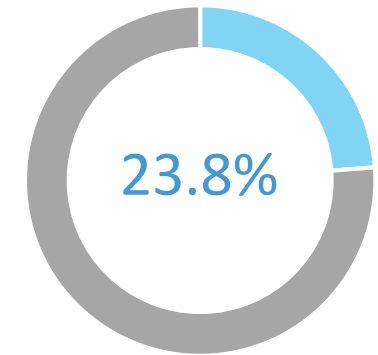
Summary of Analysis

Regimen	Resection Rate	(95% CI)
CT-only and ICT + CCRT	9.9%	(6.7, 13.5)
CT-only	7.7%	(3.1, 13.5)
ICT + CCRT	11.5%	(7.4, 16.2)
PanCO (ITT)	20.0%	(10.0, 33.7)
PanCO (PP)	23.8%	(12.1, 39.5)

Abbreviations: C.I., confidence interval; ITT, intention-to-treat (enrolled participants); PP, per protocol (enrolled and implanted participants); RR, resection rate.

PanCO Surgical Resection with Curative Intent

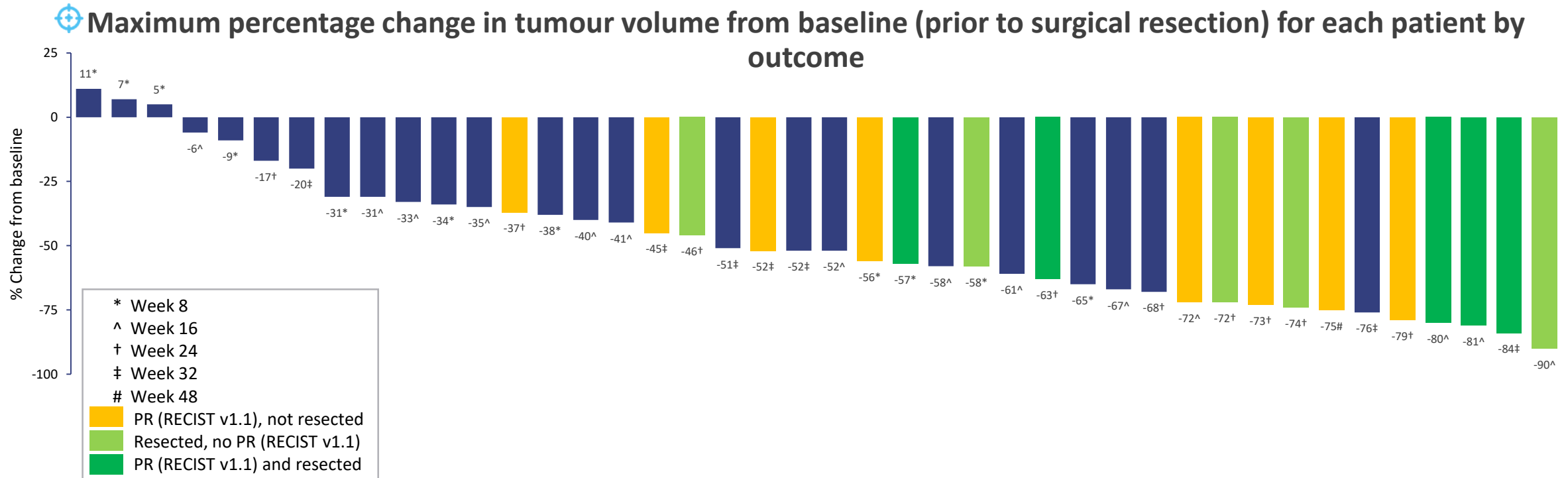
- ❖ 10 implanted study participants were restaged and subsequently had surgical resection with curative intent (PP: 23.8%; 95% CI: 12.1%, 39.5%; ITT: 20.0%; 95% CI: 10.0%, 33.7%).
- ❖ **8 of these had R0 (microscopically negative) surgical margins.**
- ❖ Mode of action of OncoSil™ may play a critical role in sterilising surgical margins.
- ❖ A further three study participants were sufficiently down-staged to be considered for surgical resection but could not proceed due to concomitant co-morbidities, advanced age etc.
- ❖ OncoSil™ treatment was associated with a reduction in size as well as a reduction in the fibrosis of tumours along blood vessels – this finding is not seen in study participants undergoing chemo-only regimens.
- ❖ **PanCO study participants undergoing surgery had favourable tissue planes, which was a surprising finding.** In study participants who have EBRT (short or long course), tissue planes often become oedematous or significantly more fibrotic, depending on the time between treatment and surgery, which can make surgery more difficult/problematic. This issue is not seen in study participants treated with OncoSil™.
- ❖ **From a surgical perspective, the use of OncoSil™ is therefore a more attractive proposition than EBRT.**
- ❖ **Surgical resection in LAPC is critical, improving the 5-year survival rate from ~5% to >20%.**



Prognostic Significance of Resected LAPC

- ⊕ Retrospective analysis of 415 patients with unresectable LAPC presenting to Johns Hopkins Hospital pancreatic multidisciplinary clinic between Jan 2013 and Sept 2017.
- ⊕ 116 (28.0% of the LAPC cohort) deemed eligible for surgical exploration either due to response by RECIST 1.1 or progression free after 4 months neoadjuvant therapy.
- ⊕ 84/116 resected (20.0% of the LAPC cohort) after median 5 months of neoadjuvant therapy.
- ⊕ 75/84 (89.0%) had R0 margin status.
- ⊕ Significantly greater use of FOLFIRINOX (63.0%), FOLFIRINOX-gemcitabine (17.0%) and radiotherapy (80.0% SBRT; 17.0% IBRT/EBRT) in resected vs. non-resected patients.
- ⊕ **Patients undergoing surgical resection had significantly better survival than patients who did not: median OS: 35.3 vs. 16.3 months and 3-year survival rate: 50.0% vs. 11.0% ($p<0.001$).**
- ⊕ **Survival significantly improved in R0 vs. R1 resections (29.3 vs. 8.1 months; $p=0.032$).**

PanCO Tumour Volumetric Assessment



Time point	Number of patients (N*/N)	Median volumetric reduction	Mean volumetric reduction (%)	Range of volumetric change (%)	p-value
Week 16	41*/42 implanted [PP]	38.0%	30.8%	+89.0% to -90.0%	<0.0001

N* = number of assessments available for Week 16 timepoint; p-value for paired T-testing of change in tumour volume from baseline to week 16. Tumour volume calculated using Longest Diameter in axial dimension, Greatest Perpendicular Diameter in axial dimension and Longest Orthogonal Diameter in craniocaudal dimension.

Summary of Key PanCO Efficacy Outcomes



⚙️ Performance (efficacy) data for the 42 study participants implanted with the OncoSil™ device demonstrate clinically relevant benefits for patients with unresectable locally advanced pancreatic cancer (LAPC).

Median OS: 16 months	LDCR _{16 weeks} 90.5%	Median PFS: 9.3 months	Median LPFS: 9.6 months	ORR: 31% DCR: 100%
Surgical Resection with Curative Intent: 23.8% R0 margin rate: 80.0%	Median tumour volumetric change: -38.0%	Median FDG-PET TLG change: -65.2%	Median CA 19-9 reduction: -77.8%	Median reduction EORTC-QLQ PAN26 Pain Scale Score at week 12: -20



1 Conclusion

OncoSil at a potential value inflection point

The Company is well positioned to realise value of OncoSil™ device

CE Mark

- CER submission following positive COC meeting
- Target CE Mark certification
- Target EU first sales

US Market Entry strategy

- Secured US FDA IDE approval
- HUD Cholangiocarcinoma secured
- HDE submission for distal cholangiocarcinoma
- OncoPaC-1 trial progress

Strategic partnerships

- Securing strategic partnerships and licensing agreements in key geographies
- Additional Licensing partners in unique geographies