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ONCOSIL™ - POTENTIAL TREATMENT FOR PANCREATIC CANCER

MAJOR UNMET NEED

OncoSil Medical has an implantable nuclear medicine device that has commenced a pivotal study in pancreatic cancer.

Localised radiation therapy is inherently safe, effective and well tolerated, ideal for pancreatic cancer.

There are highly commercially successful precedents for localised radiation therapy in liver cancer and prostate cancer.

therefore OncoSil as a localised radiation therapy for pancreatic cancer is a major opportunity for patients and investors.
About OncoSil™

- Pure beta radiation source (P32) to avoid systemic side effects
- Localised radiation therapy using sticky microparticles
- Carrier particles are inert silicon
- Particles are suspended in fluid to allow direct injection into the tumour
- Single Injection under anaesthesia takes 30 minutes
- Local radiation in the tumour lasts around 3 months
HOW ONCOSIL™ WORKS

1. Administration of ONCOSIL™ via an endoscope.
2. Delivery of beta-radiation to the tumor site.
3. Treatment of biliary and pancreatic ducts.
Endoscopic ultrasound positions the injection of OncoSil™ in the pancreatic tumour
COMPLETED PILOT STUDY

RESULTS:

- 17 locally advanced pancreatic cancer patients
- Significant tumouricidal activity with a disease control rate of 82%: 4 Partial Responses, 10 Stable disease and 3 Progressive Disease
- Average reduction in pain of 35%, with a maximum reduction of 69% between weeks 8 and 11 following implant
- Median progression free survival was 121 days
- Median overall survival was 309 days or 10+ months (compared with a typical 5.7 months with gemcitabine alone)
PANCREATIC CANCER

MAJOR UNMET CLINICAL NEED

- 280,000+ pancreatic cancer incidence yearly worldwide (1)
- Median survival ~8 months and 5-year survival less than 7%
- Severe abdominal and back pain is a significant complication in patients who develop pancreatic cancer
- Approximately 45,000 new patients diagnosed with pancreatic cancer in the US each year
- World market for pancreatic drugs is projected to exceed $1.2b by 2015 (2)
- The prognosis for patients diagnosed with pancreatic cancer regardless of stage is generally poor; the five-year survival for all stages combined is less than 7%

Source (1) – 2010 World Cancer Research Fund  Source (2) – Global Industry Analysis
MARKET FOR ONCOSIL™

Pancreatic cancer
overall Global incidence
280,000 per annum

US, Japan, Australia and Europe
192,000 p.a.

Developing world
88,000 p.a.(est)

Suitable for Oncosil™
28,800 - 47,000 p.a

Surgery, refuse the treatment, or decline for other reason
163,200 p.a.

$15,000 per treatment leads to peak sales around $300M to $500M / year
Top five oncology drugs by sales (IMS) in 2012

1. Rituximab (Rituxan®) $US 3.0B
2. Bevacizumab (Avastin®) $US 2.67B
3. Trastuzumab (Herceptin®) $US 1.66B
4. Imatinib (Gleevec®) $US 1.51B
5. Oxaliplatin (Eloxatin®) $US 1.2B
TREATMENT CHOICES FOR MOST HUMAN CANCERS

**Surgery:** Cut out the tumour:
- Only possible in 20% of PC patients

**Chemotherapy:** Poison tumour growth
Examples: Gemcitabine and Nab-paclitaxel

**Radiation therapy:** Irradiate the body
- 30 days of radiation
- Many side effects

**Immune therapy:** Disrupt growth pathways in the tumour
- Vaccines against tumour antigens
OncoSil™ particles compared with a human hair and red blood cells
ONCOSIL™ MANUFACTURE

Starting material
- Mix Silicon and Phosphorus at 1480°C
- Atomise with water to create Si-P micro particles

Create 32P Micro particles
- Grade particles to 30 microns
- Etch with acid to create porosity
- Place in a high neutron reactor

Dosing
- Package and ship in lead containers
- Pharmacist reconstitutes OncoSil™
- Patient is dosed
ONCOSIL™ INJECTION

PHARMACY RECONSTITUTES ONCOSIL™

ENDOSCOPIC ULTRASOUND GUIDED TUMOUR INJECTION
Differences between drug and device development

Drugs require Phase I, II and III clinical studies
Expensive, slow and resource intense
Typically 10 years to market (from bench)

Devices require Pilot and Pivotal studies
Faster, fewer patients, no drug interaction work
Typically 5 years to market
REGISTRATION STUDY: PANCREATIC CANCER

STUDY DESIGN

- Randomized open label clinical trial (Gold Standard)
- Combination of OncoSil with standard of care (SOC) (gemcitabine, or gemcitabine plus Abraxane) versus SOC alone
- Chemotherapy commenced within four weeks prior to implantation, or within three days following implantation
- 150 patients, randomized 100 to OncoSil plus SOC and 50 to SOC alone
- Single intra-tumoural implant of OncoSil

END POINTS

- Progression free survival, overall survival
- Quality of life substantial pain relief
- Product safety
OncoSil’s global registration strategy is with CE (Conformité Européenne) mark with the EMA (European Medicines Agency), and with the United States FDA (Food and Drug Administration PMA (pre-marketing approval). IDE: Investigational Device Exemption. PMA: Pre Marketing Approval
Multiple granted patents in US (2022), EU, Japan and elsewhere for the therapeutic product and for the manufacturing method

Trademark protection granted for OncoSil in Australia, New Zealand, UK, EU, USA, Japan and Singapore

Know-How, Expertise and Trade Secrets

- Brachytherapy clinical trial management
- Manufacturing and distribution logistics
- Detailed professional Market Research Data (Navigant Consulting Inc.)
ONCOCAL™: 2nd Generation P32

- A new technology to deliver P32 (Radioactive Phosphorus) to tumours
- Simple delivery, and significantly less cost of goods compared with OncoSil
- Multiple tumour indications
- Patent families in review covering manufacture and composition of matter
- If granted, patent protection to 2031

Class III medical device:

- Potential bioequivalence approval (510-K) with FDA using OncoSil data
A management team with experience to guide products through the global development and regulatory process.
Capital Structure

ASX code  
OSL  

Market Cap  (April 30th, 2014)  
$A34.6m

Shares on issue  
346.4m

Cash  (March 31, 2014)  
$A10.3m

No. of Shareholders  
~700
Commenced global Registration Study: Q1 2014
IDE open in the US: 2nd Half 2014
OncoCal proof of concept in animal models: 2nd Half 2014
Interim analysis for OncoSil trial: 1st Half 2015
Full patient accrual for ONC-301 Pivotal Study: 1st Half 2015
CE Mark: 1st Half 2015

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