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The Manager Company Announcements Office ASX Limited Level 6, 20 Bridge Street SYDNEY NSW 2000

#### **NeuroDiscovery to acquire Enigma Therapeutics Ltd**

- Enigma Therapeutics ("Enigma") is a cancer company based in the UK targeting the global cancer brachytherapy market which is predicted to be \$1.6 billion by 2015
- Enigma has an exclusive global license for BrachySil (to be renamed Oncosil) containing certain radioactive isotopes for use in all solid tumors from pSiMedica Ltd, a subsidiary of pSivida Corp (ASX Code PVA)
- Over the previous 10 years significant investment into the efficacy and safety of the product
- First target disease is pancreatic cancer
- Previously completed four human clinical studies in pancreatic and liver cancer
- Potentially Phase III ready, subject to regulatory discussions
- CE mark application as soon as possible, potentially during 2013
- Capital raising of \$1.5 million to accompany the acquisition resulting in available working capital of ~\$3.5 million

NeuroDiscovery Ltd (ASX: NDL), is pleased to advise that, consistent with its strategy to diversify through acquisition, the Company has today entered into a Sale and Purchase Agreement to acquire 100% of Enigma Therapeutics Ltd, a UK based cancer company.

Engima's lead product, Oncosil, is a targeted brachytherapy treatment being developed under an exclusive world-wide license from pSiMedica for its proprietary BrachySil product utilizing defined radioactive isotopes. pSiMedica is a subsidiary of USA based pSivida Corp. (ASX Code PVA).

Having already completed two Phase II studies in pancreatic cancer, a Phase III study is planned to potentially commence in calendar 2013, subject to discussions with relevant regulatory authorities.

In addition, the Company will also apply for a CE Mark as soon as possible following discussions with relevant regulatory authorities.

Key information on the Enigma technology, intellectual property and previous studies, including two studies in liver cancer, are included in Appendix A.

NeuroDiscovery will, subject to shareholder approval:

- Issue 75 million shares to purchase 100% of Enigma Therapeutics Ltd.
- Raise an additional AUS\$1.5 million via the placement of 60 million shares at \$0.025. The
  placement will be managed by Forrest Capital and is completed subject to shareholder approval.
- Issue 25 million Advisor Options (unlisted) to Forrest Capital (or its nominees) exercisable at \$0.05 per option on or before 30 June 2016.
- Issue one million options to each director on the same terms and conditions as Advisor options.

• Allow Mr Simon O'Loughlin and Mr Bret Mattes, directors of NeuroDiscovery, to participate in the capital raise for an amount not greater than \$25k per director.
A detailed Notice of Meeting will be mailed to all shareholders as soon as possible.
Yours faithfully
David McAuliffe Executive Director

#### **APPENDIX A**

#### **Oncosil - Product Background**

Oncosil (in previous trials referred to as Brachysil) is the active implantable (radiological) medical device containing radioactive phosphorus atoms (<sup>32</sup>P), which are closely bonded within an internal silicon microcrystalline structure. (<sup>32</sup>P), is a beta emitter and as such is highly cytotoxic over a short range (approximately 1 cm) but has poor penetration beyond this range. It is therefore well suited for local administration to tumors to maximize its local effects while minimizing systemic toxicity.

Oncosil is being developed for direct intratumoral implantation into solid tumors. The microparticles are designed to remain localised within the tissues and deliver a retained and targeted dose of beta radiation. The product is easy to use and administered via ultrasound guided endoscopy.

Oncosil is being developed as a medical device, not a pharmaceutical product, enabling a potentially faster route to marketing approval. The initial indication for the product is pancreatic cancer. However, many other solid tumours are potentially treatable with this therapy.

# **Enigma Initial Target Market**

Engima's strategy will be to establish proof of principle in man for Oncosil in pancreatic cancer, prior to potentially targeting further wider indications for the product. Pancreatic cancer is the fourth largest cause of cancer death in the US and Europe with an annual incidence of over 30,000 in the US and over 50,000 in the EU.

Other potential target markets include not only the use of (<sup>32</sup>P) in BrachySil but also a number of other radioisotopes approved under the assignment and license agreement.

### Previous Phase IIa and Phase IIb Clinical Data in Pancreatic Cancer

Both Phase IIa and Phase IIb clinical studies on Oncosil have already been completed.

A brief summary of both trial results is provided below.

#### Phase IIa

The Phase IIa study in patients with late stage, inoperable pancreatic cancer was completed in January 2008. This was a fixed dose study in 17 patients, with the primary objective of evaluating the safety of the product and secondary objective of assessing initial efficacy based on overall survival and progression free survival.

The trial was conducted in London (UK) and Singapore. The results from the trial, based on 24 weeks follow-up, demonstrated:

# **Product safety**

- No clinically significant product-related adverse events.
- No significant systemic leakage of (<sup>32</sup>P), from the site of implantation.

# **Product efficacy**

- CT scan analysis of patients demonstrated significant tumouricidal activity with a disease control rate of 82%.
- Reduction in pain associated with pancreatic cancer.
- Median progression free survival was 121 days.
- Median overall survival was 309 days.

The trial concluded that patients with pancreatic cancer receiving Oncosil (who are also receiving standard concomitant chemotherapy with gemcitabine) is easily deliverable, tolerable and potentially effective.

#### Phase IIb

A dose ranging study was conducted to determine the optimal dose of Oncosil. Six patients were enrolled in London (UK) and Birmingham (UK) and received either 200Gy or 400Gy as a single injection. The study was completed in August 2009.

### **Product safety**

- No clinically significant product-related adverse events.
- No significant systemic leakage of (<sup>32</sup>P), from the site of implantation.

### **Product efficacy**

• CT scan analysis of patients demonstrated significant tumouricidal activity with a disease control rate of 100%.

# **Optimized Dose**

The highest dose studied, 400Gy (4 times the dose used in the Phase IIa trial) was determined to be the optimal dose.

# **Enigma Clinical Program and Regulatory Strategy Moving Forward Under the Licence**

Engima plans to enter discussions with regulatory authorities in UK with the view to obtaining a potential CE Mark for Oncosil as soon as practicable.

The company also intends to conduct a potential Phase III study and discussions with regulatory authorities and manufacturers will take place as soon as reasonably practicable. It is anticipated this trial may have approval to commence during 2013.

# **Additional Indications for Enigma Oncosil**

In addition to pancreatic cancer, Oncosil is potentially applicable to a wide range of solid tumor indications, including tumors of the liver. pSivida previously conducted a Phase I/II and Phase IIa clinical trial in primary liver cancer which again demonstrated it was well safe and tolerated. The Phase IIa concluded that additional studies may be warranted to evaluate clinical safety and efficacy.

Enigma has the right to reference this data and information under the license agreement with pSiMedica.

# **Enigma Oncosil Manufacturing Process**

Enigma has a GMP-compliant process for the production of Oncosil with a number of manufacturing partners responsible for different aspects of the process. The starting material for the process is polycrystalline silicon which is an inexpensive and abundant raw material. The early stages of the Oncosil manufacturing process are on "cold" (ie non-radioactive) materials and partners are responsible for the atomisation, size definition and nanostructuring of the 30 micron particles and for the (<sup>32</sup>P), activation, formulation, packaging and distribution of Oncosil to trial sites.

# **Enigma Intellectual Property**

Oncosil is covered by a comprehensive portfolio of both granted patents and patent applications which all fall within the assignment and license agreement from pSiMedica. These provide broad product and technology-related protection for Enigma products and on-going development strategies.