



Date: 18th February 2020

Sydney, Australia

## Noxopharm Alliance With GenesisCare

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### Highlights

- New clinical alliance with GenesisCare to offer combined therapy of Veyonda® and <sup>177</sup>Lu-PSMA
  - <sup>177</sup>Lu-PSMA is used as a treatment for late stage prostate cancer patients
  - Both agents to be offered in a compassionate use program in Australia
  - Combination therapy may be beneficial in boosting the response to <sup>177</sup>Lu-PSMA
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**Sydney, 18th February 2020:** Noxopharm (ASX: NOX) is pleased to announce a clinical alliance with oncology services provider GenesisCare to offer a compassionate access program with Noxopharm's novel lead product candidate, Veyonda®, for patients with advanced, treatment-resistant, metastatic prostate cancer (mCRPC) being treated with theranostics.

The alliance formalises a program under which Noxopharm has been making Veyonda® available through GenesisCare for compassionate use in combination with <sup>177</sup>Lu-PSMA therapy for mCRPC patients in Australia. Following promising clinical outcomes from the compassionate use program and early clinical research, the two companies have formalised an arrangement to make the therapy available for use in patients with few treatment alternatives.

GenesisCare is one of the largest private providers of oncology services in Australia and Europe, offering a range of treatments including radiation therapy, chemotherapy, palliative radiation and nuclear medicine (theranostics).

**Professor Nat Lenzo, Clinical Director of Theranostics at GenesisCare and Clinical Professor at Curtin University said:** "Prostate cancer is the most common cancer among men in Australia, yet treatment options for advanced metastatic prostate cancer remain limited. Theranostics is offering new hope for late stage prostate cancer patients, many of whom have exhausted conventional treatment options such as chemotherapy. While further studies are required, we are seeing encouraging results from the combination of Lu-PSMA and Veyonda® in select patients requiring additional treatment effects and are grateful for Noxopharm's support to increase access to this combined therapy for suitable patients."



**Dr Gisela Mautner, Chief Medical Officer of Noxopharm, said:** “We are very pleased that Veyonda® has been identified by GenesisCare as a therapy that shows promising early signs of improved outcomes in late stage prostate cancer patients. We look forward to continuing to work closely with GenesisCare to provide Veyonda® on a compassionate use basis for the benefit of patients. Noxopharm will continue to build its research and development program for Veyonda® to document its effects in clinical trials.”

Theranostics is a new field of cancer management utilising Nuclear Medicine. Specially designed molecules are combined with a low dose diagnostic form of radiation to identify cancer location, following diagnosis these same molecules are combined with a more potent therapeutic form of radiation to kill cancer cells. Current uses for this technology include diagnosis/treatment of prostate cancer (<sup>177</sup>Lutetium-177 PSMA therapy, <sup>223</sup>Radium therapy), thyroid cancer (<sup>131</sup>Iodine therapy), and neuroendocrine tumours (<sup>177</sup>Lutetium Octreotate therapy).

Veyonda® (Idronoxil) is an experimental oncology drug that may enhance the effects of theranostic treatment with <sup>177</sup>Lutetium-PSMA (Lu-PSMA) in men with advanced prostate cancer. Theranostics with LuPSMA combines diagnostic imaging, drug delivery and response monitoring. It has been used as compassionate treatment in more than 3000 patients in Europe and Australia over the past five years and is being studied in several phase II and phase III trials in Australia and around the world. Veyonda® is a novel therapy administered twice daily for 10 days at the time of each Lu-PSMA administration.

The combination of Veyonda® and Lu-PSMA is undergoing evaluation in clinical trials, a recently announced interim analysis in patients with advanced metastatic prostate cancer suggests a very encouraging treatment response rate with a median overall survival of 17.1 months reported in these patients. Additionally, the treatment combination provides a significant reduction in pain following disease progression after conventional treatment while being well tolerated.

More information about Veyonda and the compassionate use scheme offered by GenesisCare is available from:

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### **About <sup>177</sup>Lu-PSMA**

PSMA is a protein (prostate surface membrane antigen) expressed on prostate cancer cells in about 85-90% of men with mCRPC. In management of advanced prostate cancer, prostate specific membrane antigen (PSMA)-based compounds (ligands), <sup>68</sup>Gallium PSMA and <sup>177</sup>Lutetium PSMA, are the most commonly used 'theranostic pair' for detection and treatment of metastatic disease respectively. The PSMA protein is over-expressed on prostate cancer cells and has been the subject of numerous studies highlighting its suitability as a diagnostic and therapeutic agent. <sup>177</sup>Lutetium is a radioisotope used in prostate cancer due its physical properties which facilitate tumour tissue death while avoiding unwanted effects on healthy tissue.

### **About Veyonda<sup>®</sup>**

Veyonda<sup>®</sup> is a suppository dosage form of idronoxil, a first-in-class inhibitor of sphingosine-1-phosphate (S1P). S1P is a key secondary messenger in cells, with dual roles of activating major pro-survival signalling pathways, and regulating immune cell trafficking in tissues. Many solid cancers over-express S1P, supporting unregulated tumour growth and suppressing immune cell populations and activities in tumours. By inhibiting this over-expression, idronoxil acts as both a radio-sensitiser and chemo-sensitiser, and as an immunotherapy, intended to restore immune function to tumours.

### **About the Compassionate Use Program**

In Australia, access to emerging theranostics treatment such as <sup>177</sup>Lu-PSMA and Veyonda<sup>®</sup> are via active clinical trials or with authorisation by the Therapeutic Goods Administration (TGA) Special Access Scheme (SAS), a scheme for compassionate access to medicines prior to their registration.

### **About Noxopharm**

Noxopharm is a clinical-stage Australian drug development company with offices in Sydney and New York. The Company has a primary focus on the development of Veyonda<sup>®</sup> and is the major shareholder in non-oncology drug development company, Nyrada Inc. (ASX:NYR)

[www.noxopharm.com](http://www.noxopharm.com)

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### **About GenesisCare**

GenesisCare is one of the largest private providers of oncology and cardiology services in Australia, the U.K. and Spain with 3,000 healthcare professionals and support staff across more than 150 GenesisCare centres. GenesisCare sees 160,000 people annually and carries out more than 350,000 radiation therapy treatments every year, along with treatment options including chemotherapy and theranostics. The organisation expects to more than double its reach in 2020, with the acquisition of a major U.S. oncology provider under way. [www.genescare.com](http://www.genescare.com)

The GenesisCare theranostics team is committed to developing and using targeted molecular diagnostic imaging and therapeutic agents for the diagnosis and treatment of cancers, with a focus on cancers which are difficult to treat. For details on available locations visit [genescare.com/au/theranostics/](http://genescare.com/au/theranostics/)

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*Graham Kelly, CEO and Chairman of Noxopharm has approved the release of this document to the market.*

### **Forward Looking Statements**

This announcement may contain forward-looking statements. You can identify these statements by the fact they use words such as “aim”, “anticipate”, “assume”, “believe”, “continue”, “could”, “estimate”, “expect”, “intend”, “may”, “plan”, “predict”, “project”, “plan”, “should”, “target”, “will” or “would” or the negative of such terms or other similar expressions. Forward-looking statements are based on estimates, projections and assumptions made by Noxopharm about circumstances and events that have not yet taken place. Although Noxopharm believes the forward-looking statements to be reasonable, they are not certain. Forward-looking statements involve known and unknown risks, uncertainties and other factors that are in some cases beyond the Company’s control that could cause the actual results, performance or achievements to differ materially from those expressed or implied by the forward-looking statement.