



**Date: 21 October 2019**

**Sydney, Australia**

ASX Limited  
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SYDNEY NSW 2000

### **Durable Anti-Cancer Effect Confirmed in DARRT-1 Study**

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- Data on half of study patients after 6-month review to be presented to Australian cancer conference Nov 2019
  - Data suggests major anti-cancer effect of Veyonda<sup>®</sup>/DARRT treatment regimen in late-stage prostate cancer
  - 80% of late-stage prostate cancer patients (reviewed to date) showing no disease progression after 6-months
  - 55% showing clinically significant reduction in pain at 6-months
  - DARRT-2 being planned for commencement in 2020
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**Sydney, 21 October 2019:** Noxopharm (ASX: NOX) provides an update on interim data from the DARRT-1 study where Veyonda<sup>®</sup> is being tested in patients with prostate cancer which is late-stage, progressive and metastatic and who have limited survival prospects.

This is ahead of a presentation by the Company of clinical data to the Clinical Oncology Society of Australia Annual Scientific Meeting, 12-14 November 2019.

The objective in DARRT-1 is for Veyonda<sup>®</sup> to trigger a general immune response which means achieving an anti-cancer response in the tumours in the body after delivering radiotherapy to just one or two individual tumours. The clinical objectives are greater pain relief, better quality of life, and longer survival in patients where palliative care is the current standard of care.

**The interim data indicates that the DARRT treatment regimen is on track to achieve these objectives. Cancer progression was blocked in the majority (80%) of patients (8/10 evaluable patients) over the 6-month period of observation. Also at 6-months, over half of the patients continued to experience a clinically significant reduction (mean 73%) of their pain levels.**

The DARRT treatment regimen is an experimental and novel immuno-oncology treatment where the individual effects on the immune system of low-dose radiotherapy and Veyonda<sup>®</sup> are being brought together with the aim of achieving a significantly greater effect with a whole-of-body anti-cancer outcome.

The following table summarises the data from all patients in the Study at the 3-month and 6-month review points.



	400, 800 and 1200 mg Veyonda®	
	3 months	6 months
No. of patients	22*	11**
PSA Response	7 (32%)	2 (18%)
Pain Response	12 (55%)	6 (55%)
<i>(mean pain response)</i>	<i>(78%)</i>	<i>(73%)</i>
<b><u>RECIST:</u></b>	22	10
Stable disease	13 (60%)	7 (70%)
Partial response	3 (14%)	1 (10%)
Progressive disease	2 (9%)	2 (20%)

\*DARRT-1 has two arms – a dose-escalation arm (400, 800 and 1200 mg Veyonda®) in 14 men and a dose-expansion arm (1200 mg Veyonda®) in a further 11 men. For the purpose of this analysis, all 25 men were considered as a single group. Of these, 22 had evaluable disease (tumours able to be measured radiographically), and these 22 men comprise the current data review. To date, eleven of these have completed their 6-month follow-up; the remaining 11 will complete their follow-up in mid-November 2019.

\*\*Data on remaining 11 men to be disclosed in November 2019

In DARRT-1, the patients are being followed clinically for 6 months. The long-term durability of the anti-cancer effect will be determined by observing patient survival over 24 months.

The final statistical study report is anticipated early-2020, which will contain detailed radiographic assessment of the response of both irradiated and non-irradiated tumours.

### Comments

Dr Gisela Mautner, Noxopharm Chief Medical Officer, said, "DARRT-1 is our first study in metastatic prostate cancer and the results so far are very encouraging. Considering that these patients were at the end of their treatment journey with no further treatment option available to them, it is impressive to see that the DARRT-1 treatment regimen was able to stabilise the disease progression in the majority of trial participants. Another important aspect of the DARRT-1 treatment regimen of low-dose radiotherapy plus Veyonda® is the fact that it was very well tolerated with only minor and easily manageable side effects."

Dr Graham Kelly, Noxopharm Executive Chairman, said, "We are about 3-4 weeks away from seeing the 6-month data for the final 11 patients, but even before that, we are seeing an impressive anti-cancer effect from the DARRT therapy. For men who have run out of treatment options, this



is a significant outcome. For the moment we are focusing on proving the concept of DARRT in prostate cancer, but we foresee this approach being applicable to wide range of cancers. This data helps confirm our belief that Veyonda<sup>®</sup> is on track to become an important new drug in the management of cancer more generally.”

“This has spurred us on to get underway with the next stage of trialling as quickly as possible. Our aim is to make the DARRT-2 study a U.S. and European-based study in late-stage prostate cancer, with a view to it being the study that leads to submission for marketing approval.”

#### **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 Nyrada Inc, a spin-off company developing a pipeline of non-oncology drugs.

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

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