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Sydney, Australia

Veyonda[®] Clinical Program Update & Guidance

Highlights

- DARRT-2 planning underway
 - Veyonda holding potential to be important new treatment for prostate cancer
 - Current clinical data indicating anti-cancer response in high proportion of men
 - Veyonda[®] supplies being secured
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Sydney, 13 March 2020: Noxopharm (NOX:ASX) provides an update on the planning process for its DARRT-2 clinical study and guidance on its broader clinical program for its lead product candidate, Veyonda[®].

DARRT-2 Study

Noxopharm has initiated the strategic planning process for its DARRT-2 Phase 2 study to expedite the proposed Veyonda[®] registration pathway. It has appointed a contract research organisation to provide advice on regulatory affairs matters, and current planning includes determining the overall study design, including appropriate stage of disease to be targeted, clinical endpoints, overall powering and size of the study and participating countries and sites. In addition, the Company has access to a global medical advisory board comprised of key opinion leaders in the prostate cancer field.

The Company aims to have a final clinical protocol agreed in mid-2020, with the necessary approvals being sought in the second half of 2020 ahead of a multi-national study commencing in early-2021.

Strong Veyonda[®] clinical data to date

The Company's confidence in moving forward is based on interim clinical data announced in recent months from both its DARRT-1 study (Phase 1b) and the LuPIN (Phase 1b/2a) trial, both of which provided very encouraging clinical signals and reported a very good safety profile.



Both trials have yielded clinical data suggesting that Veyonda[®] is providing the intended meaningful anti-cancer response in approximately 50% of patients, a figure that Noxopharm believes if repeated or even possibly exceeded in the DARRT-2 study would position Veyonda[®] as an important and potentially very valuable new therapy in the prostate cancer field.

In the prostate cancer market, the three most recent industry deals involved acquisitions of US\$13 billion (Medivation/Pfizer), US\$2.1 billion (Endocyte/Novartis) and US\$3.9 billion Advanced Accelerator Applications/Novartis).

Dr Gisela Mautner, Chief Medical Officer of Noxopharm, stated: “The heavy lifting has been done for several key aspects of bringing Veyonda[®] to market. We have shown that Veyonda[®] is very well tolerated and safe in the patients who have participated in our studies so far. It has also shown to be safe in our compassionate use program which involves even more progressed patients in many cases. Practicality of use and safety are major determinants for regulatory authorities and have significant impact on the success of any new drug candidate. In addition, the efficacy signals that we have measured have been very encouraging and form the basis of our planned Phase 2 study.”

Graham Kelly PhD, Noxopharm CEO, said: “Veyonda[®] is emerging as a potentially very valuable new therapy. The largest single market sector in oncology is end-stage metastatic cancer, a point at which almost every patient with metastatic cancer eventually finds themselves and is left with few treatment choices beyond palliative care. That very substantial unmet need with limited competition is where we are positioning Veyonda[®] in the first instance.”

Veyonda[®] program and commercial strategy

Noxopharm has made a strategic decision to focus on the role of Veyonda[®] in restoring immune function to tumours in conjunction with radiotherapy. While the Company will embrace broader applications of the product where appropriate, it considers the major opportunity for Veyonda[®] lies in two main areas: (i) a standard companion therapy for low-dose radiotherapy, and (ii) restoring immune function to so-called ‘cold’ tumours. The former is a major opportunity given the widespread use of low-dose radiotherapy in palliative treatment. The latter is a major area of interest in the global pharma industry given the emerging prominence of immuno-oncology therapy.

Veyonda[®] patent strategy

Noxopharm has five different families of patent applications pending. All applications were filed under the Patent Cooperative Treaty (PCT) scheme and are now in the national phase of examination. These patent applications relate to method of administration and various clinical uses. An additional patent application, in preparation, will deal with a further improvement to



the bio-active form of idronoxil that Veyonda[®] delivers. The Company continues to prosecute this wide-ranging IP strategy designed to boost the commercial value and industry attractiveness of Veyonda[®] and remains confident of securing allowance of commercially relevant claims.

Veyonda[®] supply chain

Keeping Veyonda[®] supplied to the growing number of patients reliant on treatment is a priority and the Company has adequate supplies for the foreseeable future. The Company currently is taking steps to ensure that the production line involving raw materials supply, drug synthesis and final product manufacture remains secure ahead of the DARRT-2 study and the growing compassionate use program being conducted in cooperation with GenesisCare.

About Veyonda[®]

Veyonda[®] 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 in tumours. By inhibiting the over-expression of S1P-driven pro-survival pathways, idronoxil is designed to sensitise cancer cells to the anti-cancer effects of drugs such as doxorubicin, as well as to radiation. By inhibiting the over-expression of S1P-driven exclusion of immune cells from tissues, idronoxil is designed to restore normal trafficking of immune cells.

About Noxopharm

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

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

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