



US FDA grants Orphan Drug Designation for CRO-67

- **US Food and Drug Administration grants Orphan Drug Designation for treatment of pancreatic cancer**
- **Benefits include tax credits and commercial exclusivity**
- **Supports company's development plan and commercial strategy**

Sydney, 4 October 2023: Innovative biotech company **Noxopharm Limited (ASX:NOX)** announces that the US Food and Drug Administration has granted Orphan Drug Designation (ODD) status to Noxopharm's CRO-67 preclinical drug candidate, for the treatment of pancreatic cancer.

The FDA grants ODDs for drugs designed to prevent, diagnose or treat rare diseases or conditions, and the designation comes with various benefits that include:

- Tax credits for qualified clinical trials
- Exemption from user fees (e.g. FDA application fees)
- Potential seven years of market exclusivity after approval

So far this year only two other Australian companies have received an ODD from the FDA, from a total of 260 issued.

CRO-67's designation as an orphan drug supports the company's development plan for the asset, and its future commercial value, as Noxopharm continues to build the data package that will be required for regulatory progression.

The designation comes shortly after further [encouraging CRO-67 data](#) was presented at the American Association of Cancer Research Special Conference on Pancreatic Cancer. The disease is set to become the [second leading cause of cancer-related deaths](#) in the US by 2040, and has a very poor five-year survival rate of about 9% from the time of diagnosis.

Noxopharm CEO Dr Gisela Mautner said: "For CRO-67 to achieve an ODD is a significant milestone in the development of the drug. In addition to financial benefits, the ODD will also strengthen our commercial position in a market that has seen very few new treatments over recent decades.

"Our pancreatic cancer program is a high priority, and we are committed to progressing its development as quickly as possible. Further studies are in the works, as are investigations into dosing and formulation."

-ENDS-

About Noxopharm

Noxopharm Limited (ASX:NOX) is an innovative Australian biotech company discovering and developing novel treatments for cancer and inflammation, including a pioneering technology to enhance mRNA vaccines.

The company utilises specialist in-house capabilities and strategic partnerships with leading researchers to build a growing pipeline of new proprietary drugs based on two technology platforms – Chroma™ (oncology) and Sofra™ (inflammation, autoimmunity, and mRNA vaccine enhancement).



Noxopharm also has a major shareholding in US biotech company Nyrada Inc (ASX:NYR), which focuses on drug development for cardiovascular and neurological diseases.

To learn more, please visit: noxopharm.com

Investor, Corporate & Media enquiries:

Julian Elliott

M: 0425 840 071

E: julian.elliott@noxopharm.com

Company Secretary:

David Franks

T: +61 2 8072 1400

E: David.Franks@automicgroup.com.au

Dr Gisela Mautner, CEO and Managing Director of Noxopharm, has approved the release of this document to the market on behalf of the Board of Directors.

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 (including but not limited to the COVID-19 pandemic) that could cause the actual results, performance or achievements to differ materially from those expressed or implied by the forward-looking statement.