Immediate Release

DIMERIX ANNOUNCES NEW PATENT FAMILY APPLICATION FOR DMX-700

Highlights

- New patent family application to protect key surprising outcomes observed in the DMX-700 animal study in Chronic Obstructive Pulmonary Disease (COPD)
- DMX-700 demonstrated statistically significant 80% reduction versus control in induced lung injury in mice ($p<0.01$)[1]
- In-vivo data supports progression of DMX-700 into a clinical trial, planned for first half 2023[1]
- COPD is a progressive and life-threatening lung disease and is the third leading cause of death worldwide, causing 3.23 million deaths in 2019[2]
- Global COPD treatment market was valued at almost US$18 billion in 2021 and is projected to grow at a Compound Annual Growth Rate (CAGR) of 7.28% to reach US$27 billion by 2027[3]

MELBOURNE, Australia, 09 August 2022: Dimerix Limited (ASX: DXB) a biopharmaceutical company with Phase 3 clinical studies in inflammatory diseases currently underway, today announced a new patent family application for its pipeline candidate, DMX-700, for the treatment of Chronic Obstructive Pulmonary Disease (COPD), following the recently announced 80% reduction versus control in induced lung injury in mice ($p<0.01$).[1]

In the recently announced study of DMX-700, the activity of DMX-700 was tested in mice using an oral dose delivery in the porcine pancreatic elastase (PPE) model of COPD. Pleasingly, DMX-700 resulted in a statistically significant 80% ($p<0.01$, $n=6$) reduction in the PPE-induced lung injury in mice. In contrast inhibiting only AT1R or IL-8Rβ individually had no statistically significant effect on lung injury induced by PPE.

Surprisingly, the study also identified that the use of an IL-8Rβ inhibitor along with certain doses of an angiotensin type 1 receptor blocker (ARB) were more effective in the treatment of COPD-related lung injury. Specifically, it was shown that certain doses of ARBs are more effective together with IL-8Rβ inhibitors, demonstrating an impressive 80% reduction in lung injury, but that other doses of ARBs together with IL-8Rβ inhibitors did not provide any significant effect on COPD-related lung injury. The details of the dosing will be published in due course to protect the confidential status of discovery.

Dimerix HQ
425 Smith St, Fitzroy 3065
Victoria, Australia
T. 1300 813 321
E. info@dimerix.com

As a result, Dimerix has completed another key step in securing ownership over what it believes is an important new drug discovery by lodging a new provisional patent application for DMX-700. The new provisional patent application (Australian number 2022902171), titled "Dosage regimen for the treatment of COPD", has a priority date of 02 August 2022 and if granted would expire post 2043. In accordance with normal patent prosecution process, this patent application will not become public until approximately 18 months after the priority date.

This new patent application bolsters the existing DMX-700 global patent application PCT number PCT/AU2020/050987, which was filed in September 2020.[4] It is anticipated that DMX-700 will be protected by Composition of Matter patents, Formulation patents and Method of Use patents, providing a strong competitive position.

The DMX-700 compounds individually have a known safety profile in human studies, meaning DMX-700 may potentially move directly into clinical studies, subject to regulatory approval(s). The clinical trial will now be designed, along with any further required nonclinical safety studies, with the initial clinical study expected to commence first half 2023.[1]

> "This is clearly a very exciting and busy time for Dimerix at the moment, with multiple activities that could each add significant value to the company. Our flagship Phase 3 program in FSGS is progressing well, and our second pipeline candidate, DMX-700 has demonstrated some very encouraging pre-clinical data. The DMX-700 study identified some very surprising outcomes, which we believe further strengthens our IP position moving forward. We look forward to finalising the clinical study design and anticipate initiating this study in the first half of 2023."
>
> *Dr Nina Webster, Dimerix CEO & Managing Director*

In addition, Dimerix continues to drive its flagship program, the Phase 3 ACTION3 pivotal study of DMX-200 in FSGS; support both feasibility/Phase 3 studies driven by the REMAP-CAP and CLARITY 2.0 teams for DMX-200 in COVID-19 patients; and advance the diabetic kidney disease program towards the next clinical study.

For further information, please visit our website at www.dimerix.com or contact:

Dr Nina Webster
Dimerix Limited
Chief Executive Officer & Managing Director
Tel: +61 1300 813 321
E: investor@dimerix.com

Rudi Michelson
Monsoon Communications
Tel: +61 3 9620 3333
Mob: +61 (0)411 402 737
E: rudim@monsoon.com.au

Follow us on **LinkedIn** and **Twitter**

Authorised for lodgement by the Board of the Company

—END—

About Dimerix

Dimerix (ASX: DXB) is a clinical-stage biopharmaceutical company developing innovative new therapies in areas with unmet medical needs for global markets. Dimerix is currently developing its proprietary product DMX-200, for Focal Segmental Glomerulosclerosis (FSGS), respiratory complications associated with COVID-19 and Diabetic Kidney Disease, and is developing DMX-700 for Chronic Obstructive Pulmonary Disease (COPD). DMX-200 and DMX-700 were both identified using Dimerix' proprietary assay, Receptor Heteromer Investigation Technology (Receptor-HIT), which is a scalable and globally applicable technology platform enabling the understanding of receptor interactions to rapidly screen and identify new drug opportunities. Receptor-HIT is licensed non-exclusively to Excellerate Bioscience, a UK-based pharmacological assay service provider with a worldwide reputation for excellence in the field of molecular and cellular pharmacology.

About DMX-200

DMX-200 is the adjunct therapy of a chemokine receptor (CCR2) antagonist administered to patients already receiving an angiotensin II type I receptor (AT1R) blocker - the standard of care treatment for hypertension and kidney disease. DMX-200 is protected by granted patents in various territories until 2032, with patent applications submitted globally that may extend patent protection to 2042.

In 2020, Dimerix completed two Phase 2 studies: one in FSGS and one in diabetic kidney disease, following a successful Phase 2a trial in patients with a range of chronic kidney diseases in 2017. No significant adverse safety events were reported in any trial, and all studies resulted in encouraging data that could provide meaningful clinical outcomes for patients with kidney disease. DMX-200 is also under investigation as a potential treatment for acute respiratory distress syndrome (ARDS) in patients with COVID-19.

FSGS

FSGS is a rare disease that attacks the kidney's filtering units, where blood is cleaned (called the 'glomeruli'), causing irreversible scarring. This leads to permanent kidney damage and eventual end-stage failure of the organ, requiring dialysis or transplantation. For those diagnosed with FSGS the prognosis is not good. The average time from a diagnosis of FSGS to the onset of complete kidney failure is only five years and it affects both adults and children as young as two years old.[5] For those who are fortunate enough to receive a kidney transplant, approximately 40% will get re-occurring FSGS in the transplanted kidney.[6] At this time, there are no drugs specifically approved for FSGS anywhere in the world, so the treatment options and prognosis are poor.

FSGS is a billion-dollar plus market: the number of people with FSGS in the US alone is just over 80,000,[7] and worldwide about 210,000. The illness has a global compound annual growth rate of 8%, with over 5,400 new cases diagnosed in the US alone each year[7]. Because there is no effective treatment, Dimerix has received Orphan Drug Designation for DMX-200 in both the US and Europe for FSGS. Orphan Drug Designation is granted to support the development of products for rare diseases and qualifies Dimerix for various development incentives including: seven years (FDA) and ten years (EMA) of market exclusivity if regulatory approval is received, exemption from certain application fees, and a fast-tracked regulatory pathway to approval. Dimerix reported positive Phase 2a data in FSGS patients in July 2020.

References

[1] ASX 04Jul2022

[2] WHO Fact Sheet COPD (2022) online: https://www.who.int/news-room/fact-sheets/detail/chronic-obstructive-pulmonary-disease-(copd)

[3] Chronic Obstructive Pulmonary Disease Therapeutics Market Research Report (2022) online: https://www.researchandmarkets.com/reports/4989588/chronic-obstructive-pulmonary-disease

[4] ASX 07Oct2020

5 Guruswamy Sangameswaran KD, Baradhi KM. Focal Segmental Glomerulosclerosis (July 2021), online: https://www.ncbi.nlm.nih.gov/books/NBK532272/

6 DelveInsight Market Research Report (2020); Focal Segmental Glomerulosclerosis (FSGS)- Market Insight, Epidemiology and Market Forecast -2030

7 Nephcure Kidney International (2020); Focal Segmental Glomerulosclerosis, online https://nephcure.org/livingwithkidneydisease/understanding-glomerular-disease/understanding-fsgs/