Dimerix

For Immediate Release

DMX-700 SHOWS SIGNIFICANT EFFICACY WITH 80% REDUCTION IN LUNG INJURY OF COPD

- Chronic Obstructive Pulmonary Disease (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[1]
- DMX-700 was identified for the potential treatment of COPD, with this recent study delivering promising initial results in mice
- DMX-700 demonstrated statistically significant 80% reduction versus control in induced lung injury in mice ($p<0.01$)
- In-vivo data supports progression of DMX-700 into a clinical trial, planned for first half 2023
- The 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[2]
- DMX-700 provides further potential value in addition to the Phase 3 ACTION3 pivotal study of DMX-200 in FSGS; the REMAP-CAP and CLARITY 2.0 studies in COVID-19 patients; and the diabetic kidney disease program

MELBOURNE, Australia, 4 July 2022: Dimerix Limited (ASX: DXB), a biopharmaceutical company with Phase 3 clinical studies in inflammatory diseases currently underway, is pleased to announce new data showing strong efficacy of its pipeline program, DMX-700, in an industry-standard preclinical model of chronic obstructive pulmonary disease (COPD).

DMX-700 was identified as a novel oral candidate for the treatment of COPD using Dimerix proprietary Receptor-HIT platform.[3] DMX-700 targets signalling by an Interleukin 8 receptor beta (IL-8Rβ) and an angiotensin II type 1 receptor (AT1R) heteromer in COPD using two compounds together, and achieves a synergistic effect in cells co-expressing IL-8Rβ and AT1R by blocking both receptors simultaneously.[3]

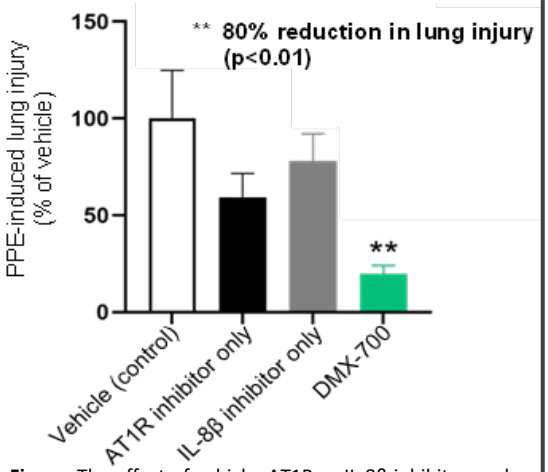

Figure: The effect of vehicle, AT1R or IL-8β inhibitors only or DMX-700 on lung injury induced by porcine pancreatic elastase (PPE) in mice. Only treatment of mice with DMX-700 resulted a statistically significant reduction (80±4.4%) in lung injury. Bars represent % of PPE only response (vehicle) mean ±S.E.M., **; p<0.01 versus vehicle, n=6 one-way ANOVA and Dunnett's multiple comparison test.

In the new study, the activity of DMX-700 was tested in mice using an oral dose delivery in the porcine pancreatic elastase (PPE) model of COPD. This model is the mostly commonly used COPD model as it mimics the inflammatory response (effect of activated neutrophils) in the lungs of mice and leads to breakdown of lung tissue and emphysema (shortness of breath). 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.

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

The very encouraging and statistically significant pre-clinical data strongly supports further development of DMX-700. Dimerix assessed three different IL-8Rβ inhibitors with an AT1R inhibitor in the pre-clinical model, with all three IL-8β inhibitors demonstrating strong efficacy outcomes and all covered by Dimerix intellectual property. Further intellectual property has been identified and an additional patent application is underway. 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.

"We have established that blocking the known targets of COPD with DMX-700 at the same time results in a statistically significant decrease in lung injury that leads to fibrosis, or scarring. These new results confirm the efficacy of DMX-700 in an industry-standard preclinical COPD model reducing lung injury by 80%. This information should provide significant encouragement to clinical investigators and patients in our planned clinical trials of DMX-700 in this devastating disease. Our now expanding clinical pipeline will strengthen our ongoing discussions with potential commercial and strategic partners"

Dr Nina Webster, Dimerix CEO & Managing Director

About Chronic Obstructive Pulmonary Disease (COPD)

COPD is a progressive and life-threatening lung disease. The most common cause of COPD is exposure to tobacco smoke (either active smoking or secondary smoke), however is also caused by exposure to indoor and outdoor air pollution, occupational dusts and fumes and long-term asthma.[1]

COPD is the third-leading cause of death in the world, causing 3.23 million deaths globally in 2019.[1] In the United States, COPD affects 1 in 8 Americans age 45 and older[4], and 1 in 20 Australia aged 45 years [5], but millions more may have the disease without even knowing it.[6] Although treatments exist to improve the symptoms of COPD, there is currently no way to slow progression of the condition or cure it.[1,4,6]

The global COPD treatment market was valued at US$17.68 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.[2]

There is a significant unmet need in COPD, which is recognised by key organisations such as the National Institutes of Health (NIH) and globally by the World Health Organization (WHO) and the Centers for Disease Control and Prevention (CDC). In 2021 the NIH released the revised COPD National Action Plan in an effort to support research, diagnosis and treatment of the disease.[4] Following this recognition, in 2018 the FDA issued revised guidance to help sponsors developing drugs to treat COPD.[4] The new guidance will enable shorter clinical trials using surrogate and patient-reported endpoints.

In addition, Dimerix continues to drive 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

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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.[7] For those who are fortunate enough to receive a kidney transplant, approximately 40% will get re-occurring FSGS in the transplanted kidney.[8] 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,[9] 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[9]. 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

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