DIMERIX COMPLETES AU$20 MILLION INSTITUTIONAL PLACEMENT FOLLOWING SUCCESSFUL INTERIM ANALYSIS IN ACTION3 PHASE 3 CLINICAL TRIAL

Investor Webinar 10.30am AEDT Tuesday 12 March 2024

You are invited to register using this link:

https://events.teams.microsoft.com/event/204c3f00-6a97-4774-b11c-9f7a5cdc39d6@3c92bf4e-76d4-4244-937b-d8ba6a8c9878

Participants may submit questions at registration or during the session

Highlights

- Dimerix has received firm commitments to raise $20 million via an institutional placement
- A significant number of new institutional investors will join the register following the placement
- Proceeds will be used to complete the ACTION3 Phase 3 clinical study in patients with FSGS, the preparation and submission of regulatory applications, as appropriate, as well as partnering activities
- ACTION3 Phase 3 trial successfully passed first interim analysis using proteinuria efficacy endpoint, confirming DMX-200 is currently performing better than placebo in reducing proteinuria (using a statistical measure[1]) in patients with FSGS in a significantly larger cohort than our prior Phase 2 study[2]
- Passing this early interim analysis suggests a statistically significant and clinically meaningful result in reducing proteinuria at the end of the study may be possible[2,3]
- ACTION3 clinical trial will now formally expand into Part 2 of the study, with new clinical sites to open in additional countries, including China, to further enhance recruitment
- Dimerix will now focus on the execution of potential licensing deals for available jurisdictions, including in the US and China

MELBOURNE, Australia, 12 March 2024: Dimerix Limited (ASX: DXB, "**Dimerix"**), is today pleased to announce that it has received binding commitments from a significant number of new and existing institutional and sophisticated investors and other exempt investors for a share placement of 66,666,667 fully paid ordinary shares (Placement Shares) at an issue price of A$0.30 (30 Australian cents) per Placement Share to raise $20 million (before costs) (Placement).

The issue price of A$0.30 represents a nil discount to the Company's last traded price before the release of this announcement, a premium of 29.2% to the 30-day VWAP (A$0.232), a premium of 14.5% to the 5-day VWAP (A$0.262) and a 52 week share price high. Euroz Hartleys acted as the sole Lead Manager of the Placement.

The Placement follows the news that the ACTION3 Phase 3 trial of DMX-200 in patients with focal segmental glomerulosclerosis (FSGS) was successful in the pre-specified interim analysis of the proteinuria (efficacy) endpoint from the trial's first 72 randomised patients. The analysis indicated that, using a statistical measure,[1] DMX-200 is performing better than placebo in terms of reducing proteinuria (a surrogate marker of kidney disease progression[4]) in patients with FSGS. This analysis is extremely valuable as it is based on a significantly larger cohort than the prior Dimerix Phase 2 study which was conducted in 8 patients.[1]

Funds raised under the Placement are proposed to be used for the following purposes:

- Clinical studies, including:
    - ACTION3 Phase 3 clinical trial in patients with FSGS;
    - Preparation and submission of appropriate regulatory applications as and when applicable to continue FSGS Phase 3 clinical study; and
    - Continued manufacturing distribution and logistics of the required clinical trial material
- Transaction/partnering activities; and
- Working capital and offer costs

The Placement Shares are expected to be issued on or about Wednesday, 20 March 2024.

"We are delighted to welcome our new Institutional and sophisticated investors, and we appreciate the strong support from existing shareholders.

This Placement was highly strategic as it provides sufficient funds to take Dimerix through the 2nd interim analysis and, including eligible R&D rebates, the completion of the ACTION3 Phase 3 clinical trial.

If the next interim analysis is compelling, the Company could seek to apply for accelerated marketing approval in certain jurisdictions.

By completing this Placement, Dimerix has not only accessed funding from high quality institutional investors to deliver on its Phase 3 program, but also significantly strengthened its balance sheet and this puts us in a strong negotiating position with potential partners, particularly on the back of our successful interim analysis just announced."

Dr Nina Webster, CEO & Managing Director, Dimerix

The 66,666,667 Placement Shares will all be issued under the placement capacity available to the Company under Listing Rule 7.1, with none issued under Listing Rule 7.1A.

An Appendix 3B containing further details of the Placement has been released to ASX in conjunction with, and at or about the same time as, this announcement.

Dimerix has received a significant amount of partnering interest from pharma companies globally, with its first licence agreement entered into with Advanz Pharma in October 2023 for Europe, Canada, Australia and New Zealand, and valued at up to $230 million plus royalties on sales. Dimerix has received several non-binding term sheets for other regional deals, with multiple parties currently in the data room conducting due diligence and negotiating a potential licensing agreement for various territories. Following the successful first interim analysis, Dimerix will focus on the execution of potential licensing deals for those available jurisdictions including in the US and China.

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

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Authorised for lodgement with ASX by the Board of Dimerix

-ENDS-

About ACTION3 FSGS Phase 3 Study

The Phase 3 study, which is titled **"A**ngiotensin II Type 1 Receptor (AT1R) & **C**hemokine Receptor 2 (CCR2) **T**argets for **I**nflammat**o**ry **N**ephrosis", or ACTION3 for short, is a pivotal (Phase 3), multi-centre, randomised, double-blind, placebo-controlled study of the efficacy and safety of DMX200 in patients with FSGS who are receiving a stable dose of an angiotensin II receptor blocker (ARB). Once the ARB dose is stable, patients will be randomized to receive either DMX200 (120 mg capsule twice daily) or placebo.

The single Phase 3 trial in FSGS patients has a second interim analysis point built in that is designed to capture evidence of proteinuria and kidney function (eGFR slope) during the trial, aimed at generating sufficient evidence to support marketing approval.

Further information about the study can be found on ClinicalTrials.gov (Study Identifier: NCT05183646) or Australian New Zealand Clinical Trials Registry (ANZCTR) (Study Identifier ACTRN12622000066785).

About Dimerix

Dimerix (ASX: DXB) is a clinical-stage biopharmaceutical company working to improve the lives of patients with inflammatory diseases, including both kidney and respiratory diseases. Dimerix is currently focussed on developing its proprietary Phase 3 product candidate DMX-200 (QYTOVRA® in some territories), for Focal Segmental Glomerulosclerosis (FSGS) kidney disease, and is also developing DMX-700 for Chronic Obstructive Pulmonary Disease (COPD). DMX-700 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.

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 addition to any exclusivity period that may apply in key territories. 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.

About 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 60% 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 limited.

FSGS is a billion-dollar plus market: the number of people with FSGS in the US alone is just over 80,000,[5] and worldwide about 220,000.[7] The illness has a global compound annual growth rate of 8%, with over 5,400 new cases diagnosed in the US alone each year.[8] 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 *Predictive Power statistical model, using industry standard as set by the independent renal biostatistician consultant for Dimerix*

2 *Interim analysis data does not guarantee a statistically significant outcome at the end of the trial*

3 *Ciolino JD, Kaizer AM, Bonner LB (2023); Guidance on interim analysis methods in clinical trials; J Clin Transl Sci.; 7(1): e124. doi: 10.1017/cts.2023.552*

4 *Haider M, Aslam A (2023) Proteinuria; PMID: 33232060 online https://pubmed.ncbi.nlm.nih.gov/33232060/*

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

6 *Front. Immunol., (July 2019) | https://doi.org/10.3389/fimmu.2019.01669*

7 *Delve Insight Market Research Report (2022): Focal segmental glomerulosclerosis (FSGS) – Market Insight, Epidemiology and market forecast – 2032; https://www.delveinsight.com/report-store/focal-segmental-glomerulosclerosis-fsgs-market;*

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