For Immediate Release

DIMERIX QUARTERLY ACTIVITIES REPORT

Quarter highlights and operational activities

- Dimerix successfully passed first efficacy Interim Analysis[1]
  - ACTION3 Phase 3 trial successfully passes first interim analysis using proteinuria efficacy endpoint
  - DMX-200 is currently performing better than placebo in reducing proteinuria (using a statistical measure[2]) in patients with FSGS in a significantly larger cohort than our prior Phase 2 study[3]
  - 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[3,4]
  - IDMC has again noted no safety concerns to date, which is entirely consistent with the existing and growing strong safety profile of DMX-200
  - The IDMC recommended the ACTION3 clinical trial continue unchanged
- Dimerix received correspondence from the FDA in April 2024 reconfirming eGFR as the 104-week (final) endpoint
- Dimerix completed AU$20 million Institutional Placement[5]
- Dimerix presented at the Euroz Hartley Rottnest Island Institutional Conference[6]
- Dimerix presented at the ASX Small & Mid-Cap Conference[7]
- Cash position of AU$35.2 million at 31 March 2024
- Net operating cash outflow for the March quarter was AU$3.3 million

MELBOURNE, Australia, 22 April 2024: Dimerix Limited (ASX: DXB) ("Dimerix" or the "Company"), a clinical-stage biopharmaceutical company with late-stage clinical assets, today announced its Appendix 4C and Quarterly Activities Report for the period ended 31 March 2024.

During the quarter, Dimerix announced 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,[2] DMX-200 is performing better than placebo in terms of reducing proteinuria (a surrogate marker of kidney disease progression[8]) in patients with FSGS. The ACTION3 clinical trial has formally expanded into Part 2 of the study and to date, the study has randomised and dosed 98 patients with FSGS.

Dimerix ended the quarter with cash of $35.2 million ($14.8 million at 31 December 2023), with net operating cash outflows for the period of $3.3 million ($7.8 million net operating cash inflows in the prior quarter). Cash outflow for the period predominately related to clinical and CMC costs related to the Phase 3 FSGS Study.

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

Additionally, during the quarter, Dimerix successfully raised $20M via an institutional placement, resulting in a significant number of new institutional investors joining the Company's register. Dimerix also received approximately $4.8 million in relation to the exercise of unlisted and listed options (the material terms of the options are set out in the Prospectus' as lodged with ASIC and released to ASX on 4 May 2023 and 26 June 2023).

In accordance with Listing Rule 4.7C, payments made to related parties and their associates included in item 6.1 of the Appendix 4C incorporates director fees and salary (including superannuation) for the CEO and Managing Director and Non-Executive Directors.

FSGS Phase 3 study

Dimerix remains focussed on developing its lead Phase 3 product candidate DMX-200 (QYTOVRA® in some territories). In March 2024, Dimerix announced 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 indicates that, using a statistical measure,[2] DMX-200 is performing better than placebo in terms of reducing proteinuria (a surrogate marker of kidney disease progression[8]) 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.[3]

An interim analysis incorporating a futility assessment (where certain data are assessed early to determine whether or not the drug is having a desired effect) is included to ensure a trial does not continue unnecessarily if there is no efficacy signal.[4] Therefore passing the first interim analysis (which was a futility assessment) is important as it suggests that it is possible DMX-200 may achieve a statistically significant and clinically meaningful result at the end of the study.[3]

After notifying the Company of the interim analysis results, the trial's Independent Data Monitoring Committee (IDMC) additionally stated that it had no safety concerns relating to DMX-200 and formally recommended the trial continue as planned. The ACTION3 Phase 3 trial in FSGS kidney disease patients continues to recruit across clinical sites globally.

The ongoing Phase 3 is a double-blind, randomised (1:1) trial and is currently being conducted across multiple study sites in more than 11 countries, with the primary endpoints currently being both eGFR and proteinuria. Proteinuria (the measure of how much protein is in the urine), is used along with the estimated glomerular filtration rate (eGFR) in both the classification of kidney diseases and the effectiveness of therapies. Proteinuria can serve as an indicator of renal disease, and the degree of proteinuria correlates with disease progression.[8]

Project PARASOL is a collaborative international effort which has been established with the aim to define the quantitative relationships between short-term changes in biomarkers (such as proteinuria and GFR) and long-term outcomes for FSGS patients and further support the use of alternative proteinuria-based endpoints as a basis to provide both accelerated and traditional approval in FSGS kidney disease.[9] Dimerix is supporting this working group, with Dimerix and other industry sponsors invited to participate in workshops to be held in June 2024 and October 2024. The outcomes of PARASOL may support and/or influence the ACTION3 endpoints and the study's statistical analysis plan.

Post quarter end in April 2024, Dimerix received correspondence from the Food and Drug Administration (FDA) in the US which among general trial conduct and regulatory related commentary, noted PARASOL's ongoing work and recommended that Dimerix continue the ACTION3 trial "*to support a traditional approval based on an eGFR-based endpoint and/or other clinically meaningful endpoint(s)*" while the PARASOL activities are taking place during 2024. The FDA have "*acknowledged the ongoing international effort [of PARASOL] to support the use of proteinuria as a basis for accelerated approval*".

As previously announced, patients, physicians and Dimerix staff will remain blinded to patient allocation (i.e. which patients are receiving DMX-200 and which are receiving placebo) at all times during study, including at the second interim analysis timepoint which will assess the statistical powering of the ACTION3 study. The potential for accelerated (or conditional) approval submissions in, or around, 2025 following the second interim analysis (and any required unblinding) will be assessed based on project PARASOL outcomes, recommendations of the IDMC (based on review of emerging data from ACTION3) and subsequent discussions with the appropriate regulatory authorities such as the FDA in the US.

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.[10] 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.

About the trial

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 DMX-200 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.

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

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 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).

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 blood pressure 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.[11] For those who are fortunate enough to receive a kidney transplant, approximately 60% will get re-occurring FSGS in the transplanted kidney.[12] 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 potential billion-dollar plus market: the number of people with FSGS in the US alone is just over 80,000,[11] and worldwide about 220,000.[13] The illness has a global compound annual growth rate of 8%, with over 5,400 new cases diagnosed in the US alone each year.[14] 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 release 11Mar24
2 Predictive Power statistical model, using industry standard as set by the independent renal biostatistician consultant for Dimerix
3 Interim analysis data does not guarantee a statistically significant outcome at the end of the trial
4 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
5 ASX release 12Mar24
6 ASX release 13Mar24
7 ASX release 27Mar24
8 Haider M, Aslam A (2023) Proteinuria; PMID: 33232060 online https://pubmed.ncbi.nlm.nih.gov/33232060/
9 See Project PARASOL website: https://www.is-gd.org/parasol
10 ASX release 05Oct23
11 Guruswamy Sangameswaran KD, Baradhi KM. (2021) Focal Segmental Glomerulosclerosis), online: https://www.ncbi.nlm.nih.gov/books/NBK532272/
12 Front. Immunol., (July 2019) | https://doi.org/10.3389/fimmu.2019.01669
13 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;
14 Nephcure Kidney International (2020); Focal Segmental Glomerulosclerosis, online https://nephcure.org/livingwithkidneydisease/understanding-glomerular-disease/understanding-fsgs/

Appendix 4C

Quarterly cash flow report for entities subject to Listing Rule 4.7B

Name of entity	
DIMERIX LIMITED	
ABN	**Quarter ended ("current quarter")**
18 001 285 230	31/03/2024

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (9 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	-	10,872
1.2	Payments for		
	(a) research and development	(2,695)	(12,401)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	-	-
	(d) leased assets	-	-
	(e) staff costs	(162)	(436)
	(f) administration and corporate costs	(435)	(1,635)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	50	88
1.5	Interest and other costs of finance paid	(2)	(240)
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	-	8,971
1.8	Other (GST)	(19)	808
1.9	**Net cash from / (used in) operating activities**	**(3,263)**	**6,027**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	(5)	(11)
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	-	-

Consolidated statement of cash flows		Current quarter $A'000	Year to date (9 months) $A'000
2.2	Proceeds from disposal of:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	-	-
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	-	-
2.3	Cash flows from loans to other entities	-	-
2.4	Dividends received (see note 3)	-	-
2.5	Other (provide details if material)		
2.6	**Net cash from / (used in) investing activities**	**(5)**	**(11)**

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3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	20,000	20,281
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	4,833	5,207
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(1,140)	(1,394)
3.5	Proceeds from borrowings	-	-
3.6	Repayment of borrowings	-	(2,843)
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other (provide details if material)	(6)	(29)
3.10	**Net cash from / (used in) financing activities**	**23,687**	**21,222**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	14,810	7,992
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(3,263)	6,027
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(5)	(11)

Consolidated statement of cash flows		Current quarter $A'000	Year to date (9 months) $A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	23,687	21,222
4.5	Effect of movement in exchange rates on cash held	4	3
4.6	**Cash and cash equivalents at end of period**	**35,233**	**35,233**

5.	Reconciliation of cash and cash equivalents at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	Current quarter $A'000	Previous quarter $A'000
5.1	Bank balances	5,254	786
5.2	Call deposits	29,979	14,024
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
5.5	**Cash and cash equivalents at end of quarter (should equal item 4.6 above)**	**35,233**	**14,810**

6.	Payments to related parties of the entity and their associates	Current quarter $A'000
6.1	Aggregate amount of payments to related parties and their associates included in item 1	171
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-

Note: if any amounts are shown in items 6.1 or 6.2, your quarterly activity report must include a description of, and an explanation for, such payments.

The amount at 6.1 includes Director fees and salary (including superannuation) for the CEO and Managing Director and Non-Executive Directors.

7.	**Financing facilities** *Note: the term "facility' includes all forms of financing arrangements available to the entity.* *Add notes as necessary for an understanding of the sources of finance available to the entity.*	**Total facility amount at quarter end $A'000**	**Amount drawn at quarter end $A'000**
7.1	Loan facilities		
7.2	Credit standby arrangements	-	-
7.3	Other (please specify)	-	-
7.4	**Total financing facilities**		

7.5	**Unused financing facilities available at quarter end**	-
7.6	Include in the box below a description of each facility above, including the lender, interest rate, maturity date and whether it is secured or unsecured. If any additional financing facilities have been entered into or are proposed to be entered into after quarter end, include a note providing details of those facilities as well.	

8.	**Estimated cash available for future operating activities**	**$A'000**
8.1	Net cash from / (used in) operating activities (item 1.9)	(3,263)
8.2	Cash and cash equivalents at quarter end (item 4.6)	35,233
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	35,233
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	N/A

Note: if the entity has reported positive net operating cash flows in item 1.9, answer item 8.5 as "N/A". Otherwise, a figure for the estimated quarters of funding available must be included in item 8.5.

8.6 If item 8.5 is less than 2 quarters, please provide answers to the following questions:

8.6.1 Does the entity expect that it will continue to have the current level of net operating cash flows for the time being and, if not, why not?

Answer: N/A

8.6.2 Has the entity taken any steps, or does it propose to take any steps, to raise further cash to fund its operations and, if so, what are those steps and how likely does it believe that they will be successful?

Answer: N/A

8.6.3 Does the entity expect to be able to continue its operations and to meet its business objectives and, if so, on what basis?

Answer: N/A

Note: where item 8.5 is less than 2 quarters, all of questions 8.6.1, 8.6.2 and 8.6.3 above must be answered.

Compliance statement

1 This statement has been prepared in accordance with accounting standards and policies which comply with Listing Rule 19.11A.

2 This statement gives a true and fair view of the matters disclosed.

Date: 22 April 2024

Authorised by: Board of Directors
(Name of body or officer authorising release – see note 4)

Notes

1. This quarterly cash flow report and the accompanying activity report provide a basis for informing the market about the entity's activities for the past quarter, how they have been financed and the effect this has had on its cash position. An entity that wishes to disclose additional information over and above the minimum required under the Listing Rules is encouraged to do so.

2. If this quarterly cash flow report has been prepared in accordance with Australian Accounting Standards, the definitions in, and provisions of, *AASB 107: Statement of Cash Flows* apply to this report. If this quarterly cash flow report has been prepared in accordance with other accounting standards agreed by ASX pursuant to Listing Rule 19.11A, the corresponding equivalent standard applies to this report.

3. Dividends received may be classified either as cash flows from operating activities or cash flows from investing activities, depending on the accounting policy of the entity.

4. If this report has been authorised for release to the market by your board of directors, you can insert here: "By the board". If it has been authorised for release to the market by a committee of your board of directors, you can insert here: "By the [*name of board committee – eg Audit and Risk Committee*]". If it has been authorised for release to the market by a disclosure committee, you can insert here: "By the Disclosure Committee".

5. If this report has been authorised for release to the market by your board of directors and you wish to hold yourself out as complying with recommendation 4.2 of the ASX Corporate Governance Council's *Corporate Governance Principles and Recommendations*, the board should have received a declaration from its CEO and CFO that, in their opinion, the financial records of the entity have been properly maintained, that this report complies with the appropriate accounting standards and gives a true and fair view of the cash flows of the entity, and that their opinion has been formed on the basis of a sound system of risk management and internal control which is operating effectively.