For Immediate Release

DIMERIX QUARTERLY ACTIVITIES REPORT

Quarter highlights and operational activities

- Dimerix Announced License Agreement for DMX-200 for the treatment of Focal Segmental Glomerulosclerosis (FSGS) in the European Economic Area, the UK, Switzerland, Canada, Australia, and New Zealand[1]
- Dimerix to receive up to ~AU$230 million[2] in upfront and milestone payments, plus royalties
    - €6.5 million (~AU$10.8 million[2]) in upfront payment within 30 days of agreement
    - up to €132 million (~AU$219 million[2]) in potential milestones
    - tiered royalties on net sales
- Dimerix Appointed Chief Medical Officer[3]
- FDA Approved Qytovra Brand Name[4]
- Regulatory Approval received in Malaysia for ACTION3 Study[5]
- Dimerix Received AU$8.9M R&D Tax Incentive Rebate[6]
- Successful Completion of 2nd DSMB Review of FSGS Trial[7]
- Dimerix presented at Bioshares Biotech Summit[8]
- DMX-200 FSGS PH3 Kidney Trial Part 1 Outcome set for March 2024[9]
- Approval received for Paediatric Investigation Plan from EMA[10]
- Dimerix confirmed Phase 3 study design appropriate for China[11]
- Cash position of AU$6.8 million at 30 September 2023
- Net operating cash inflow for the September quarter was AU$1.5 million

MELBOURNE, Australia, 30 October 2023: 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 30 September 2023. During the quarter Dimerix entered into its first license agreement for the commercialisation of Dimerix' Phase 3 drug candidate, DMX-200, in focal segmental glomerulosclerosis (FSGS) kidney disease, following regulatory approval in Europe, Canada, Australia and New Zealand. In addition, Dimerix continued to recruit patients to its lead global program, ACTION3 Phase 3 clinical study in FSGS. With randomisation of the first cohort of patients complete, the Part 1 interim outcome expected is to be announced on, or around, 15 March 2024.[12]

Dimerix ended the quarter with cash of $6.8 million ($8.0 million at 30 June 2023), with net operating cash inflows for the period of $1.5 million ($4.3 million net operating cash outflows in the prior quarter). Cash outflow for the period predominately related to Clinical and CMC costs related to the Phase 3 FSGS Study, offset by $8.9 million received in relation to the FY23 R&D Tax Incentive.

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

Following receipt of the FY23 R&D Tax Incentive funds, Dimerix repaid the outstanding Radium Capital R&D loan balance of circa. $2.8 million plus associated fees and interest, resulting in a net cash benefit of approximately $5.8 million.

Additionally, post quarter end, Dimerix announced an exclusive license agreement for the European Economic Area, the UK, Switzerland, Canada, Australia, and New Zealand for the commercialisation of Dimerix' Phase 3 drug candidate DMX-200 for the treatment of FSGS. As part of the license agreement, Dimerix will receive an upfront payment of €6.5 million (~AU$10.8 million[2]) within 30 days of executing the agreement, plus potential development and commercialisation milestones of up to €132 million (~AU$219 million[2]). In addition, Dimerix is eligible to receive tiered, escalating, mid-teen to twenty percentage royalties on net sales of DMX-200 if successfully commercialised.

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 directors' fees, salaries and superannuation.

FSGS Phase 3 study

Dimerix is currently focussed on developing its proprietary Phase 3 product candidate DMX-200 (QYTOVRA® in some territories). The ACTION3 Phase 3 trial in FSGS kidney disease patients continues to recruit across clinical sites globally.

The single Phase 3 trial in FSGS patients has two interim analysis points built in that are designed to capture evidence of proteinuria and kidney function (eGFR slope) during the trial, aimed at generating sufficient evidence to support accelerated marketing approval. A successful outcome in the first interim analysis outcome, expected on or around 15 March 2024,[12] would see the Company announce a clinically significant and statistical meaningful improvement in proteinuria in patients on DMX-200 vs placebo and that the trial is continuing to Part 2. On success, the study will then proceed formally into Part 2, with additional clinical sites expected to open in further countries, including China.

As part of Dimerix' active business development program, in October, Dimerix entered into its first licensing agreement for DMX-200 in FSGS. The ADVANZ Pharma team has a proven record in developing and commercialising medicines in areas with no approved therapies and high unmet needs. Furthermore, ADVANZ Pharma's expertise and resources will be invaluable in supporting Dimerix to complete development and commercialise DMX-200.

Dimerix retains all rights to DMX-200 in all other territories, and the company continues to pursue and progress licensing opportunities with potential partners outside the licensed territories.

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 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.

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

—END—

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.[13] For those who are fortunate enough to receive a kidney transplant, approximately 60% will get re-occurring FSGS in the transplanted kidney.[14] 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,[13] and worldwide about 220,000.[15] The illness has a global compound annual growth rate of 8%, with over 5,400 new cases diagnosed in the US alone each year.[16] 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 05Oct2023*
2 *Based on exchange rate of 1 EUR = 1.66034 AUD as at 04 October 2023*
3 *ASX release 23Oct2023*
4 *ASX release 2Sep2023*
5 *ASX release 22Sep2023*
6 *ASX release 13Sep2023*
7 *ASX release 08Aug2023*
8 *ASX release 24Jul2023*
9 *ASX release 24Jul2023*
10 *ASX release 05Jul2023*
11 *ASX release 03Jul2023*
12 *Current independent Data Safety Monitoring Board (DSMB) scheduled meeting*
13 *Guruswamy Sangameswaran KD, Baradhi KM. (2021) Focal Segmental Glomerulosclerosis), online: https://www.ncbi.nlm.nih.gov/books/NBK532272/*
14 *Front. Immunol., (July 2019) | https://doi.org/10.3389/fimmu.2019.01669*
15 *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;*
16 *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	30/09/2023

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (3 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	-	-
1.2	Payments for		
	(a) research and development	(7,205)	(7,205)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	-	-
	(d) leased assets	-	-
	(e) staff costs	(117)	(117)
	(f) administration and corporate costs	(486)	(486)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	4	4
1.5	Interest and other costs of finance paid	(238)	(238)
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	8,971	8,971
1.8	Other (GST)	595	595
1.9	**Net cash from / (used in) operating activities**	**1,524**	**1,524**

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

Consolidated statement of cash flows		Current quarter $A'000	Year to date (3 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**	**-**	**-**

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	281	281
3.2	Proceeds from issue of convertible debt securities		
3.3	Proceeds from exercise of options	-	-
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(134)	(134)
3.5	Proceeds from borrowings	-	
3.6	Repayment of borrowings	(2,843)	(2,843)
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other (provide details if material)	(14)	(14)
3.10	**Net cash from / (used in) financing activities**	**(2,710)**	**(2,710)**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	7,992	7,992
4.2	Net cash from / (used in) operating activities (item 1.9 above)	1,524	1,524
4.3	Net cash from / (used in) investing activities (item 2.6 above)	-	-

Consolidated statement of cash flows		Current quarter $A'000	Year to date (3 months) $A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(2,710)	(2,710)
4.5	Effect of movement in exchange rates on cash held	3	3
4.6	**Cash and cash equivalents at end of period**	**6,809**	**6,809**

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	6,223	6,930
5.2	Call deposits	586	1,062
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)**	**6,809**	**7,992**

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	140
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)	1,524
8.2	Cash and cash equivalents at quarter end (item 4.6)	6,809
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	6,809
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: 30 October 2023

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.