Dimerix

For Immediate Release

DIMERIX QUARTERLY ACTIVITIES REPORT

Quarter highlights and operational activities

- Potential upside for Dimerix with choice of approval endpoint for its ACTION3 Phase 3 clinical trial (subject to FDA agreement), following Project PARASOL workshop preliminary data analysis indicating reduction in proteinuria alone may be an appropriate full FDA approval endpoint[1]
- 129 patients have currently been randomised/dosed in the ACTION3 Phase 3 clinical trial, with 16 patients in stabilisation, titration or screening ahead of potential randomisation (subject to meeting inclusion criteria)
- Recruitment remains on-track with blinded interim analysis for the first 144 patients currently expected around mid-CY2025
- National Registry of Rare Kidney Diseases (RaDaR) engaged to enhance ACTION3 trial recruitment across UK[2]
- Expert nephrologist and Co-Chair of the PARASOL working group, Dr Laura Mariani, appointed to Dimerix Medical Advisory Board[1]
- Expert paediatric nephrologist, Dr Howard Trachtman, appointed to Medical Advisory Board[3]
- First paediatric site activated[3]
- First patients completed ACTION3 and entered into Open Label Extension study[4]
- Adolescent Dose confirmed for ACTION3 Clinical Trial[5]
- Dimerix presented as the keynote speaker at Bio Connections Australia[6]
- Dimerix presented at Bioshares Biotech Summit, and received the Blake Award for Excellence 2024[7]
- Dimerix received AU$0.53 million upfront payment from Taiba and approximately $1.16 million in relation to the exercise of listed options
- Cash position of AU$19.2 million at 30 September 2024
- FY24 R&D tax incentive rebate of $7.9 million anticipated Q4 CY2024[8]
- Net operating cash outflow for the September quarter was AU$4.08 million
- Dimerix continues to receive strong partnering interest in DMX-200

MELBOURNE, Australia, 31 October 2024: Dimerix Limited (ASX: DXB) (“Dimerix” or the “Company”), a biopharmaceutical company with a Phase 3 clinical asset in kidney disease, today announced its Appendix 4C and Quarterly Activities Report for the period ended 30 September 2024. During the quarter Dimerix continued to make significant progress with its lead program, ACTION3 Phase 3 clinical trial in focal segmental glomerulosclerosis (FSGS), opening up a number of additional clinical sites globally. This has been another key quarter for the program, as clinical site initiation is fundamental to the overall operational success of a clinical trial. The ACTION3 clinical trial is currently recruiting across 17 of the 19 planned countries. The full study recruitment target is 286 patients, with 129 currently randomised/dosed in the ACTION3 Phase 3 clinical trial and 16 patients in stabilisation, titration or screening ahead of potential randomisation (subject to meeting inclusion criteria), collectively leading to the 144 patients required for Part 2 analysis of the trial.

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

Dimerix ended the quarter with cash of $19.18 million ($22.1 million at 30 June 2024), with net operating cash outflows for the period of $4.08 million. During the quarter, Dimerix received AU$0.53 million upfront payment from Taiba Middle East FZ LLC in relation to the exclusive license agreement, for the United Arab Emirates (UAE), Saudi Arabia, Oman, Kuwait, Qatar, Bahrain and Iraq for the commercialisation of Dimerix' Phase 3 drug candidate DMX-200 for the treatment of FSGS. This is the second license agreement Dimerix has entered into for DMX-200, and under the terms of the agreement with Taiba, Dimerix may be eligible to receive up to AU$120.5 million in upfront and milestone payments[9], in addition to royalties. Additionally, during the quarter, Dimerix received approximately $1.16 million in relation to the exercise of 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, bonus and salary (including superannuation) for the CEO and Managing Director and Non-Executive Directors.

Project PARASOL

The PARASOL (**P**roteinuria **a**nd GF**R** as Clinical Trial Endpoints in Foc**a**l **S**egmental Gl**o**merulosc**l**erosis) working group is a collaborative academic and regulator-led international effort that has been established with the aim to define the quantitative relationships between changes in biomarkers such as proteinuria and eGFR 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 marketing approval in FSGS kidney disease.[10] Dimerix is supporting this working group, including participating in workshops held in June 2024 and October 2024.

The October 2024 PARASOL Scientific Workshop, which included clinicians, patients, key opinion leaders, statisticians, FDA and industry sponsors of FSGS clinical trials, presented a preliminary analysis of the pooled globally available observational data of FSGS patients. It is important to note that the PARASOL data set uses observational data, is broad ranging, includes patients across a wide range of demographics, age and regions, and is not specifically limited to randomised trial data with the same population as the Dimerix ACTION3 Phase 3 clinical trial.

The PARASOL project team presented the preliminary data analysis at the American Society of Nephrology (ASN) meeting in San Diego on 25th October 2024, with the analysis confirming, amongst other things, the strong correlation between the surrogate endpoint of improvement in eGFR and the clinical endpoint of reduced risk of end-stage kidney disease, noting eGFR is currently the primary endpoint in its ACTION3 Phae 3 clinical trial.

It was also broadly recognised that patients with FSGS, unlike other types of kidney disease, often have residual scarring of the kidney that may prevent some patients reaching the low level of proteinuria seen in other kidney diseases (where complete remission is defined as <0.3 g/g protein in the urine). The PARASOL dataset has now shown that higher proteinuria thresholds including 0.7 g/g, 1.0 g/g, and up to 1.5 g/g have shown significant benefit with regard to reducing risk of progression

to renal failure. Importantly, this provides a range of potential proteinuria targets for new drug candidates targeting FSGS, subject to FDA confirmation.

There was general agreement from the FDA at the workshop that PARASOL working group has likely provided sufficient data to support the relationship between a reduction in proteinuria and decreased risk of progression. The FDA may now have sufficient data to grant full FDA approval on these proteinuria endpoints. However, it is likely each industry sponsor will have to present justification to the FDA for which proposed proteinuria threshold should be applicable to their drug candidate, along with their drug candidate safety profile and the biological plausibility for how their drug candidate directly works to reduce proteinuria and/or preserve kidney function.

For Dimerix and its ACTION3 Phase 3 clinical trial, the potential benefit is that it is likely that the Company may now have a range of proteinuria endpoints that could be acceptable as a primary endpoint for full FDA approval, subject to FDA confirmation. Importantly, no changes are anticipated to the study, as it is already collecting both eGFR and proteinuria data for a total of 2 years. With regards to next steps, Dimerix intends on requesting a meeting with the FDA to reach agreement on the appropriate proteinuria endpoints for DMX-200 in the ACTION3 Phase 3 clinical trial.

ACTION3 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.[11] The analysis indicated that, using a statistical measure,[12] DMX-200 was performing better than placebo in terms of reducing proteinuria (a surrogate marker of kidney disease progression[16]) 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.[13]

Following the first interim analysis results, the ACTION3 Phase 3 trial in FSGS kidney disease patients continues to recruit across clinical sites globally, with approximately 170 clinical sites planned globally. During the period, Dimerix focused on the opening a number of those additional clinical sites, before initiating the patient recruitment and screening process once opened. Clinical site opening is typically the most significant cost of a clinical study,[14,15] and consequently it should be noted that clinical trial spend is not linear with expenditure higher in some periods than others. In addition, given a number of territories around the world require compulsory access to the experimental treatment for patients as they complete a clinical trial, following the successful Part 1, Dimerix now has an open label extension (OLE) study in place. The OLE will allow all patients access to DMX-200 once they have completed the ACTION3 clinical trial and follow them for a further 2 years. This provides further study risk mitigation and long-term data.

The ongoing Phase 3 is a double-blind, randomised (1:1) trial and is currently being conducted across multiple study sites globally, with the primary endpoints currently being both estimated glomerular filtration rate (eGFR) and proteinuria. Proteinuria (the measure of how much protein is in the urine),

is used along with the 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.[16]

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).

Partnering

Partnering discussions continue to progress across various regions, with the potential for multiple agreements globally. Following its two licencing agreements entered into with 1) Advanz Pharma in October 2023 for Europe, Canada, Australia and New Zealand, and valued at up to $230 million plus royalties on sales[17]; and 2) Taiba in May 2024 for the Middle East territories and valued up to $120 million plus royalties on sales[18], Dimerix continues to receive strong partnering interest in DMX-200.

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.[19] For those who are fortunate enough to receive a kidney transplant, approximately 60% will get re-occurring FSGS in the transplanted kidney.[20] 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,[19] and worldwide about 220,000.[21] The illness has a global compound annual growth rate of 8%, with over 5,400 new cases diagnosed in the US alone each year.[22] 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 28 October 2024
2 ASX release 16 September 2024
3 ASX release 12 September 2024
4 ASX release 10 September 2024
5 ASX release 04 July 2024
6 ASX release 29 July 2024
7 ASX release 12 July 2024
8 Subject to ATO review
9 Based on US dollar conversions & further terms outlined in ASX Announcement on 27 May 2024
10 See Project PARASOL website: https://www.is-gd.org/parasol
11 ASX release 11Mar24
12 Predictive Power statistical model, using industry standard as set by the independent renal biostatistician consultant for Dimerix
13 Interim analysis data does not guarantee a statistically significant outcome at the end of the trial
14 The Impact on Clinical Site Budgeting, IQVIA White Paper (2023), https://www.iqvia.com/-/media/iqvia/pdfs/library/white-papers/sky-high-inflation-and-the-great-resignation-impact-on-clinical-site-budgeting.pdf
15 Sertkaya, A (2016), Key cost drivers of pharmaceutical clinical trials in the United States, Clinical Trials 13(2) DOI:10.1177/1740774515625964
16 Haider M, Aslam A (2023) Proteinuria; PMID: 33232060 online https://pubmed.ncbi.nlm.nih.gov/33232060/
17 ASX release 05Oct23
18 ASX release 27May2024
19 Guruswamy Sangameswaran KD, Baradhi KM. (2021) Focal Segmental Glomerulosclerosis), online: https://www.ncbi.nlm.nih.gov/books/NBK532272/
20 Front. Immunol., (July 2019) | https://doi.org/10.3389/fimmu.2019.01669

21 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;
22 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	30/09/2024

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	527	527
1.2	Payments for		
	(a) research and development	(4,672)	(4,672)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	-	-
	(d) leased assets	-	-
	(e) staff costs	(271)	(271)
	(f) administration and corporate costs	(757)	(757)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	67	67
1.5	Interest and other costs of finance paid	(4)	(4)
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	-	-
1.8	Other (GST)	1,027	1,027
1.9	**Net cash from / (used in) operating activities**	**(4,083)**	**(4,083)**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	(2)	(2)
	(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**	**(2)**	**(2)**

-

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	-
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	1,159	1,159
3.4	Transaction costs related to issues of equity securities or convertible debt securities	-	-
3.5	Proceeds from borrowings	-	-
3.6	Repayment of borrowings	-	-
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other (provide details if material)	(29)	(29)
3.10	**Net cash from / (used in) financing activities**	**1,130**	**1,130**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	22,141	22,141
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(4,083)	(4,083)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(2)	(2)

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)	1,130	1,130
4.5	Effect of movement in exchange rates on cash held	(3)	(3)
4.6	**Cash and cash equivalents at end of period**	**19,183**	**19,183**

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	2,314	1,517
5.2	Call deposits	16,869	20,624
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)**	**19,183**	**22,141**

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	314
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, salary and bonuses (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)	(4,083)
8.2	Cash and cash equivalents at quarter end (item 4.6)	19,183
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	19,183
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	4.7

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: 31 October 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.