For Immediate Release

DIMERIX QUARTERLY ACTIVITIES REPORT

Quarter highlights and operational activities

- ACTION3 FSGS Phase 3 clinical trial Part 1 recruitment achieved[1]
- ACTION3 FSGS Phase 3 clinical trial currently recruited 92 patients globally
- Dimerix received $6.0M R&D Tax Incentive Rebate[2]
- ACTION3 Part 1 interim analysis, which will assess proteinuria reduction of the first 72 patients on DMX-200 versus placebo at week 35, is anticipated in the latter half of calendar year 2023[1]
- FDA confirms inclusion of paediatrics in ACTION3 trial appropriate[3]
- CLARITY 2.0 COVID-19 trial primary endpoint outcome announced[4]
- Dimerix presented at AusBioInvest, highlighting FSGS ACTION3 program[5]
- Dimerix presented at BioEurope partnering conference, the largest gathering of global pharma companies outside the US
- Non-Executive Chairman resigned[6]
- Cash position of $5.7 million at 31 December 2022
- Net operating cash flow for the December quarter was -$375,000

MELBOURNE, Australia, 31 January 2023: Dimerix Limited (ASX: DXB) ("Dimerix" or the "Company"), a clinical-stage biopharmaceutical company with multiple late-stage clinical assets, today announced its Appendix 4C and Quarterly Activities Report for the period ended 31 December 2022. During the quarter Dimerix continued to make significant progress with its lead program, ACTION3 Phase 3 clinical trial in focal segmental glomerulosclerosis (FSGS). A significant milestone was achieved during the quarter, with the first 72 patients (Part 1) recruited in ACTION3 phase 3 pivotal clinical trial of DMX-200 in the treatment FSGS kidney disease.

Dimerix ended the quarter with cash of $5.7 million ($6.1 million at 30 September 2022), with net operating cash outflows for the period of $375,000 ($3.5 million net operating cash outflows in the prior quarter). Cash outflow for the period predominately related to clinical and manufacturing costs related to the Phase 3 FSGS trial, offset by $6.0 million received in relation to the FY22 R&D Tax Incentive.

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. Dimerix continues to assess its capital requirements moving forward, including the potential for a cash advance from an approved R&D loan facility.

By advancing its ACTION3 clinical program in FSGS, Dimerix continues deliver on its commitment towards bringing the potential benefits of DMX-200 to these patients globally, while building value for its stakeholders.

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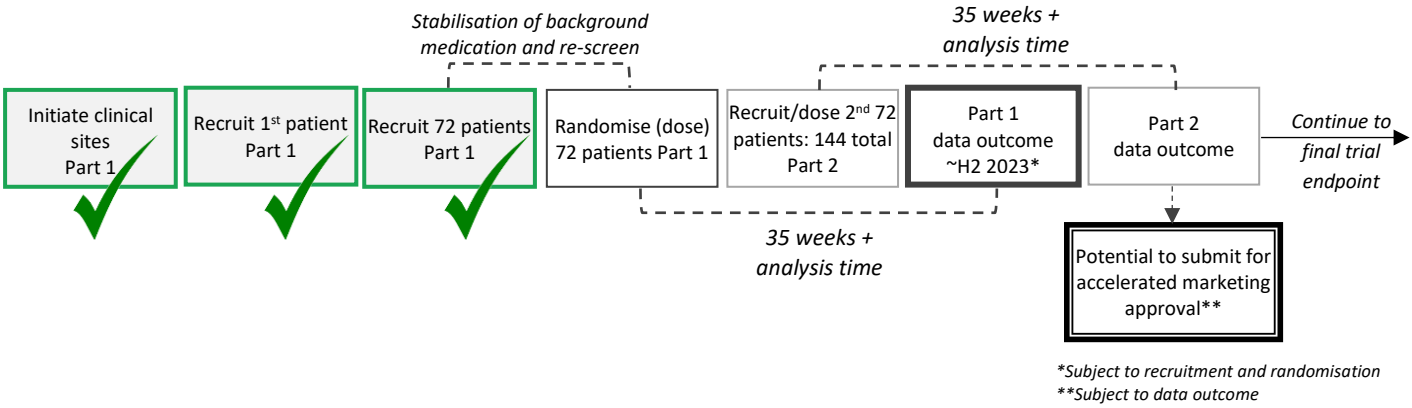
FSGS Phase 3 trial - ACTION3 FSGS CLINICAL STUDY

The ACTION3 Phase 3 trial is actively recruiting across clinical sites globally, with 92 patients having now been recruited to its DMX-200 Phase 3 trial in patients with FSGS kidney disease as at 31 January 2023 (versus 48 as at 27 October 2022[7]). Once patients have completed the background medication stabilisation period and subsequent re-screening, they are then randomised to receive either drug or placebo. The trial continues to recruit patients for any screen failures, patients who drop out or do not comply with the clinical trial protocol and to support Part 2 of the trial.[1]

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.[1] Part 1 interim analysis of the trial data will conclude once 72 patients have completed 35 weeks treatment.



About the trial

The Phase 3 trial, 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 trial 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, aged 18 to 80 years (broadening to 12 to 80 years[3]), will be randomized to receive either DMX-200 (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).

COVID-19 clinical studies

During the period, CLARITY 2.0 reported on the primary endpoint of the trial.[4] DMX-200 was safe and well-tolerated, with no notable variation in the incidence or severity of adverse events between treatment with DMX-200 or placebo. There were no serious adverse events related to the drug reported. The safety data findings are entirely consistent with existing and growing strong safety profile of DMX-200. At Day 14, 92% of participants did not require hospitalisation and had no limitation on activities (score of 1 on the Health Score Scale) in both arms (Primary Endpoint), and 4%

in each group were not hospitalised but had limitation on activities (score of 2 on the Health Score Scale).

Given the low-risk patient population recruited, there was interest in exploring alternative endpoints including time to oxygen free status defined as the time to a score of 3 or less. The median time to oxygen free status was 4 days in the DMX-200 group and 5 days in the placebo group. The median length of hospital stay was 6 days in the DMX-200 group and 6 days in the placebo group. The trial was halted early due to recruitment challenges driven in part by falling rates of hospitalised COVID-19. Dimerix remains focussed on its flagship FSGS program and does not intend to continue development for DMX-200 in COVID-19 beyond commitments to CLARITY 2.0 and REMAP-CAP.

Chronic obstructive pulmonary disease program

On 4 June 2022, Dimerix announced that its pipeline candidate, DMX-700, resulted in a statistically significant 80% ($p<0.01$, $n=6$) reduction in lung injury in mice. The very encouraging and statistically significant pre-clinical data strongly supported further development of DMX-700. Additional non-clinical activities to assess pharmacokinetics and dosing were conducted during the period that may support entry of the asset into the clinic once complete.

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

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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.[8] For those who are fortunate enough to receive a kidney transplant, approximately 60% will get re-occurring FSGS in the transplanted kidney.[9] 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,[8] and worldwide about 220,000.[10] The illness has a global compound annual growth rate of 8%, with over 5,400 new cases diagnosed in the US alone each year.[11] 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 15Dec22*
2 *ASX release 25Oct22*
3 *ASX release 12Jan23*
4 *ASX release 13Dec22*
5 *ASX release 27Oct22*
6 *ASX release 23Dec22*
7 *4C ASX release 27Oct22*
8 *Guruswamy Sangameswaran KD, Baradhi KM. (2021) Focal Segmental Glomerulosclerosis), online: https://www.ncbi.nlm.nih.gov/books/NBK532272/*
9 *Front. Immunol., (July 2019) | https://doi.org/10.3389/fimmu.2019.01669*
10 *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;*
11 *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	31/12/2022

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (6 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	-	-
1.2	Payments for		
	(a) research and development	(6,223)	(9,351)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	-	-
	(d) leased assets	-	-
	(e) staff costs	(112)	(293)
	(f) administration and corporate costs	(364)	(873)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	21	27
1.5	Interest and other costs of finance paid	(1)	(2)
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	6,069	6,083
1.8	Other (GST)	235	499
1.9	**Net cash from / (used in) operating activities**	**(375)**	**(3,910)**

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

Consolidated statement of cash flows		Current quarter $A'000	Year to date (6 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)**

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	-	-
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)	(13)	(26)
3.10	**Net cash from / (used in) financing activities**	**(13)**	**(26)**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	6,105	9,630
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(375)	(3,910)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	-	(2)

Consolidated statement of cash flows		Current quarter $A'000	Year to date (6 months) $A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(13)	(26)
4.5	Effect of movement in exchange rates on cash held	(3)	22
4.6	**Cash and cash equivalents at end of period**	**5,714**	**5,714**

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	603	1,731
5.2	Call deposits	5,111	4,374
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)**	**5,714**	**6,105**

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	144
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)	(375)
8.2	Cash and cash equivalents at quarter end (item 4.6)	5,714
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	5,714
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	15.2

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 January 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.