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For Immediate Release

DIMERIX QUARTERLY ACTIVITIES REPORT

Quarter highlights and operational activities

- AGM held on 27 September 2021
- Phase 3 global study in FSGS kidney patients commenced with first ethics and regulatory approval
- DMX-200 CLARITY COVID-19 study expanded into Australia
- DMX-200 CLARITY COVID-19 study approved in India
- Successful $4 million Share Purchase Plan closed oversubscribed
- Successful $20 million Placement to fund phase 3 trials announced
- DMX-200 COVID-19 study opened more sites in Europe and UK
- >400 patients recruited to the REMAP-CAP RAAS inhibition domain to date
- FDA confirmed phase 3 study endpoints in FSGS kidney disease
- Cash position of $8.7 million at 30 September 2021 (not including Placement Tranche 2 and SPP funds received in October)
- Net operating cash flow for the September quarter was -$4.8 million

MELBOURNE, Australia, 25 October 2021: 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 30 September 2021. During the quarter, Dimerix made significant operational progress, in line with the strategic plan.

Dimerix ended the quarter with cash of $8.7 million ($5.3 million at 30 June 2021), with net operating cash outflows for the period of $4.8 million, which was in line with company expectations ($3.2 million net operating cash outflows in the prior quarter). The increase in total operating cash outflow for the quarter relative to the prior period is a result of increased clinical and manufacturing expenditure.

During the quarter, Dimerix received $13.7 million relating to the settlement of Tranche 1 and partial settlement of Tranche 2 Placement. Additionally, Dimerix repaid the $5 million loan facility held with its major shareholder, Mr Peter Meurs, which had been in place since March 2021.

Dimerix also received $10.3 million after the quarter end relating to settlement of the SPP and remaining Tranche 2 allocation, which is not reflected in the 4C-Quartlerly Cashflow.

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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.

Cost management remains a key priority for the business, with the cost base being carefully managed to ensure delivery of a sustainable business beyond the current milestones. Dimerix remains focused on building shareholder value by advancing clinical trials to provide treatments globally for patients with serious and life-threatening inflammatory diseases, with three Phase 3 clinical trials under way, two in COVID-19 patients with respiratory complications and one in Focal Segmental Glomerulosclerosis (FSGS), a rare kidney disease.

FSGS Phase 3 study - ACTION3

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 (final), 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, aged 18 to 75 years, will be randomized to receive either DMX-200 (120 mg capsule twice daily) or placebo. Manufacturing of DMX-200 finished product and matching placebo for the study is also complete. The first patient is expected to be enrolled in the quarter ending December 2021.

During the quarter, ethics submissions were made in Australia and New Zealand, and the first ethics and regulatory approvals were announced on 21 October 2021. IQVIA, the appointed lead Contract Research Organisation (CRO), is the largest global CRO and has extensive and recent experience in running late-stage global FSGS clinical studies, and clinical sites will be initiated country by country, based on a number of factors including speed of regulatory submissions. Submissions in other territories, including US and Europe, are anticipated in this quarter.

REMAP-CAP Feasibility/Phase 3 study

The REMAP-CAP study is an investigator-led study in patients with COVID-19 pneumonia, driven by a consortium of global trialists, clinicians and experts through the study sponsor, REMAP-CAP. Participants in the ACE2 RAS study domain are randomised to receive one of three different RAS blockade treatment arms, including the DMX-200 arm, or a control.

Over 400 patients have been recruited to the RAAS inhibition domain, with Europe and UK currently experiencing an increase in case numbers as the territory enters the colder months.

As announced on 03 September 2020, Dimerix was awarded $1 million from MTPConnect's Biomedical Translation Bridge (BTB) program provided by the Australian Government's Medical Research Future Fund, with support from UniQuest, to support DMX-200 inclusion in this study.

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CLARITY 2.0 Feasibility/Phase 3 study

The CLARITY 2.0 study is an investigator initiated, prospective, multi-centre, randomised, double blind, placebo-controlled study, which aims to enrol 600 patients diagnosed with COVID-19. The study is open for recruitment in India following DCGI approval (ASX 24 September 2021) and will expand to sites in Australia once ethics approval is received (ASX 15 October 2021). An interim safety analysis will be conducted after the first 80 patients have been recruited in sites in India.

Dimerix supports both studies driven by the REMAP-CAP and CLARITY 2.0 teams including supply of DMX-200. Dimerix looks forward to reporting on progress and as key milestones are met.

Dimerix has multiple assets in commercially attractive and growing markets that have a high unmet need, and with no current marketed competition, and with a potential fast pathway to market. Dimerix continues to progress the multiple Phase 3 programs, as well as further progress the diabetic kidney disease, COVID-19 and COPD programs.

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.

In 2020, Dimerix completed two Phase 2 studies: one in FSGS and one in diabetic kidney disease, following a successful Phase 2a study in patients with a range of chronic kidney diseases in 2017. No significant adverse safety events were reported in any study, 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.

Respiratory Complications associated with COVID-19

Patients hospitalised with COVID-19 typically have acute lung dysfunction due to the immune response to the virus. However, while the long-term effects on the lung from COVID-19 remain largely unknown, it is widely accepted that COVID-19 will result in acute injury in the same way as previous coronavirus infections such as SARS and MERS. As such, it is likely to result in chronic lung fibrosis in many patients, leading to poor quality of life, high ongoing hospitalisation requirements and ultimately a poor prognosis.

Globally, and prior to COVID-19, respiratory distress affected more than 3 million people a year in 2019 accounting for 10-15% of intensive care unit admissions, and approximately 200,000 patients each year in the United States.[1] The market size of Acute Respiratory Distress Syndrome (ARDS) in the seven major markets was expected to grow to US$934.81 million in 2026.[2] However, it is also likely to grow further as a result of the 2020 pandemic. The death rate associated with ARDS is high, with overall mortality between 30 and 40%.[1] The estimated average costs of treatment in an ICU unit with artificial ventilation total approximately US$100,000 per patient, with the average length of stay in ICU as a result of ARDS being 25 days, and the average length of hospitalisation being approximately 47 days.[3] However, there are also significant costs associated with additional post-discharge treatment. There is no known prevention of ARDS currently available, nor is there any known cure.

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.[4] For those who are fortunate enough to receive a kidney transplant, approximately 40% will get re-occurring FSGS in the transplanted kidney.[5] 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,[6] and worldwide about 210,000. The illness has a global compound annual growth rate of 8%, with over 5,400 new cases diagnosed in the US alone each year[6]. Because there is no effective treatment, Dimerix has received Orphan Drug Designation for DMX-200 in both the US and Europe for FSGS. This is a special status granted to a drug to treat a rare disease or condition; the designation means that DMX-200 can potentially be fast-tracked, and receive tax and other concessions to help it get to market.

DMX-200 for FSGS has been granted Orphan Drug Designation by the FDA and EMA. 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 an abbreviated regulatory pathway to approval.

Dimerix reported positive Phase 2a data in FSGS patients in July 2020.

References

[1] REMAP-CAP background: https://www.remapcap.org/background

[2] https://www.prnewswire.com/news-releases/acute-respiratory-distress-syndrome-ards-market-to-reach-usd-934-8-million-by-2026--reports-and-data-300940537.html

[3] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4261619/

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

[5] DelveInsight Market Research Report (2020); Focal Segmental Glomerulosclerosis (FSGS)- Market Insight, Epidemiology and Market Forecast -2030

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

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Appendix 4C

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

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Name of entity	
DIMERIX LIMITED	
ABN	**Quarter ended ("current quarter")**
18 001 285 230	30/09/2021

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	(4,356)	(4,356)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	-	-
	(d) leased assets	-	-
	(e) staff costs	(107)	(107)
	(f) administration and corporate costs	(516)	(516)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	-	-
1.5	Interest and other costs of finance paid	(200)	(200)
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	144	144
1.8	Other (GST)	242	242
1.9	**Net cash from / (used in) operating activities**	(4,793)	(4,793)

2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	(4)	(4)
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	-	-

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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**	**(4)**	**(4)**

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	13,661	13,661
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	180	180
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(589)	(589)
3.5	Proceeds from borrowings	-	-
3.6	Repayment of borrowings	(5,000)	(5,000)
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other (provide details if material)	(12)	(12)
3.10	**Net cash from / (used in) financing activities**	**8,240**	**`8,240**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	5,250	5,250
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(4,793)	(4,793)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(4)	(4)

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)	8,240	8,240
4.5	Effect of movement in exchange rates on cash held	2	2
4.6	**Cash and cash equivalents at end of period**	**8,695**	**8,695**

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	626	359
5.2	Call deposits	8,069	4,891
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)**	**8,695**	**5,250**

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	210
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 salaries (including superannuation).

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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)	(4,793)
8.2	Cash and cash equivalents at quarter end (item 4.6)	8,695
8.3	Unused finance facilities available at quarter end (item 7.5)	
8.4	Total available funding (item 8.2 + item 8.3)	8,695
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	1.8

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: Future net operating cash flows is expected to be consistent with current levels of net operating cash flows.

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: Yes, the Company received Tranche 2 Placement funds and Share Purchase Plan funds in October 2021. Additionally, the Company expects to receive its FY20/21 R&D Tax Incentive rebate in the December quarter.

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: Yes, the Company expects to continue operations and meet its business objectives.

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.

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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: 25 October 2021

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.

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