For Immediate Release

DIMERIX SHAREHOLDER UPDATE

MELBOURNE, Australia, 20 October 2020: Dimerix Limited (ASX: DXB), a clinical-stage biopharmaceutical company, provides its Shareholder Update which is appended to this announcement.

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

Authorised for lodgement by the Board of the Company

—END—

Dimerix

20 October 2020

Dimerix Shareholder Update

"We have now completed three Phase 2 studies that all show efficacy in a group of patients with active inflammatory disease and we are working towards progressing DMX-200 into a Phase 3 clinical study in FSGS in the first half of 2021."

Dr Nina Webster
CEO & Managing Director

Despite the challenges that all businesses face from the global pandemic, we are continuing in 2020 to make meaningful progress in developing our lead drug candidate, DMX-200, a process that began in 2017 when Dimerix first sent DMX-200 into development as a potential therapy for chronic kidney disease.

To recap, we have DMX-200 in three clinical development programs: diabetic kidney disease (DKD); focal segmental glomerulosclerosis (FSGS); and acute respiratory distress syndrome (ARDS) in COVID-19 patients. Each of these is a potentially transformational program in its own right.

DMX-200 in Kidney Disease

FSGS and DKD are progressive and irreversible diseases, with patients ultimately requiring dialysis or transplant. Dimerix believes for both diseases, DMX-200 can potentially delay end-stage kidney failure and extend patients' lives.

We understand that DMX-200 works in these chronic kidney diseases by reducing damage caused by inflammatory cells, and this is supported by all clinical data to date. It does this by blocking the "signalling" process by which inflammatory cells move to the kidney, and prevents subsequent onset of fibrosis (scarring), by which chronic kidney disease progresses. DMX-200 works by disrupting the mechanisms driving inflammatory processes and disease progression. We have demonstrated this effectiveness through DMX-200's ability to reduce the levels of protein in the urine, which is a sign of kidney damage.

Healthy kidneys should only allow tiny amounts to enter the urine from the blood, as most protein molecules are too large for the kidney's filters, the glomeruli. Therefore, the presence of protein in the urine (or "proteinuria") acts as a warning signal that not all is well with the kidneys. In other words, if you can reduce the amount of protein in the urine, it demonstrates the progression of kidney failure has been slowed.

Each study conducted by Dimerix to date has demonstrated a reduction in proteinuria in the majority of patients, when compared to the standard-of-care therapy. Most recently, results from our two Phase 2 studies, for FSGS and DKD, showed a statistically and clinically significant association between the drug treatment and reduction in proteinuria.

The DKD results were consistent with prior studies showing that patients with marginally higher starting levels of albuminuria showed statistically significant improvement in their levels of albumin while being treated with DMX-200. Reducing proteinuria (of which albuminuria is a subset) should translate to a slowing of disease progression.

DMX-200 Phase 2 Clinical Study Results

The two 2020 studies were run on the back of very compelling data seen in our previous Phase 2a study, conducted in 2017, and we were very pleased to report positive study results from both the FSGS study and the DKD study that were consistent with our prior studies, and that continue to support the development of DMX-200 in these kidney diseases.

The Phase 2a FSGS trial showed that 86% of patients demonstrated a reduction of proteinuria with DMX-200 versus placebo; a 29% reduction in proteinuria (grouped analysis) across all patients receiving DMX-200 compared to placebo; and 29% of patients achieved a fall of more than 40% in proteinuria levels on DMX-200, when compared to placebo.

Similarly, the DKD trial was focused on the patients' levels of 'albuminuria,' or presence of albumin in the urine, a specific protein. In patients who had marginally higher levels of albuminuria (over 57 milligrams per mmol (mg/mmol)), more than 60% saw reduction against placebo. The overall percent mean reduction of protein in the urine in those DKD patients on DMX-200 versus placebo was both statistically and clinically significant, and was in addition to the current standard-of-care treatment.

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

We know that our drug works on the inflammatory process: it "needs" this process to start working. In our DKD trial, we looked at groups of patients with very early diagnosis of kidney disease – and thus, the earliest stages of any inflammatory process.

One of those groups had baseline levels of albuminuria above 57mg/mmol (equivalent to 500 milligrams of albuminuria per gram), which is a recognised clinically relevant threshold for treatment of kidney disease, while another group included in the study had baseline levels as low as 30mg/mmol, which is also a recognised threshold for treatment. These levels both represent early diagnosis.

Although prior studies also had the 30mg/mmol inclusion criteria, this is the first exploratory study that enrolled diabetic patients with baseline albuminuria below 100mg/mmol. We had a large number of patients that had albuminuria levels near the lowest 30mg/ mmol threshold that did not appear to respond to DMX-200. That is good to know: patients may not even be diagnosed with kidney disease until they have over 57mg/mmol albuminuria.

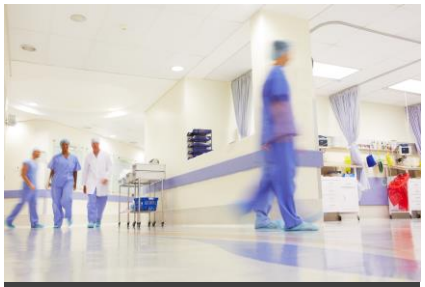
We learned that there was a statistically significant trend shown between treatment effect in patients that entered the study with a baseline albuminuria value above 57mg/mmol, compared to those with lower baseline levels of albuminuria below 57mg/mmol.

In the sub-group above 57mg/mmol starting albuminuria there were more than 60% of patients showing a reduction in albuminuria level and of those, 56% achieving a greater than 25% reduction in albuminuria versus placebo.

Based on this data, the "need" for a higher starting blood albuminuria level (>57mg/mmol) to get to work on an inflammatory response seems to have been confirmed. Sadly, kidney disease is a progressive disease, and function will decline over time: the difference between 30mg/mmol and 57mg/mmol of blood albuminuria level is small on the scale of predicted kidney decline, and often represents only a few months of kidney disease progression. We believe that our drug, if administered on diagnosis of kidney disease over 57mg/mmol blood albuminuria level, may delay the need for dialysis by three to five years.

This goes to the heart of (a) how our drug works; and (b) what our drug can do for kidney disease patients.

The most important thing from the Phase 2 FSGS and DKD study results is that they build on the positive outcome of our prior Phase 2a study of DMX-200 in chronic kidney disease, and further validate DMX-200 as a therapeutic candidate. The positive results suggest that treatment with DMX-200 may indeed result in clinically meaningful improvements in kidney function when added to the standard-of-care in patients with FSGS and DKD. This has been a positive research progression along a carefully planned and executed program.



Both Phase 2 trials showed that DMX-200 was effective in patients with early diagnosis of the respective kidney diseases.

In this context, it is important to understand what Phase 2 studies are trying to do. Phase 2 studies are designed to inform the design of Phase 3 studies, and that is exactly what our 2020 studies have done. The data from both the FSGS and DKD studies support progression of DMX-200 into pivotal Phase 3 clinical trials.

We expect to submit an Investigational New Drug (IND) application to the US Food & Drug Administration (FDA) for a Phase 3 clinical study in FSGS in the first half of 2021, and initiate the study on clearance from the FDA, as well as determine the next stages of development for diabetic kidney disease.

The Dimerix Medical Advisory Board believes that these data put DMX-200 in a great position in the global development efforts for new treatments for FSGS. This is fantastic news for those patients diagnosed with FSGS, their families and their physicians. The Medical Advisory Board has also received the full data set from both the FSGS and the DKD trial, and is in the process of interpreting the relationship between the treatment effect seen in these studies and other patient factors, such as other medications, prognostic biomarkers or legacy effect. This analysis will help to inform the design of the planned FSGS Phase 3 study. We will make this analysis public as soon as it is complete.

In Australia, Dimerix supplies DMX-200 to FSGS and DKD patients through "compassionate use," as part of the Therapeutic Goods Administration's (TGA's) Special Access Scheme, or SAS. There are patients that have been on the treatment since 2017; and some patients from both our recent FSGS and DKD trials will also stay on the treatment. Patients' doctors have to re-apply regularly for the SAS to continue: we believe the fact that physicians are willing to complete this paperwork process repeatedly indicates that they see real benefit to their patients from the treatment.

DMX-200 in global COVID-19 Trial

In addition to the DKD and FSGS renal programs, we are working on a study in patients with Acute Respiratory Distress Syndrome (ARDS), which is a major cause of death associated with COVID-19. The trial, known as the Randomised, Embedded, Multifactorial Adaptive Platform trial for Community-Acquired Pneumonia (REMAP-CAP) program, is endorsed by the World Health Organization (WHO). The REMAP-CAP trials have been established by a worldwide group of intensive care specialists, to enable researchers to analyse multiple different treatment options for eligible COVID-19 patients admitted to ICU, comprising 30 partner organisations and 260 sites across 16 countries, with more than 7,000 patients across the entire study.

Seeing DMX-200 start to work on an inflammatory response also speaks to why we expect it to work in ARDS with COVID-19, as well.

DMX-200 was selected based on overwhelming scientific rationale and its unique potential to treat COVID-related issues. In our DKD and FSGS trials, DMX-200 has shown a mechanism of increased treatment effect at higher levels of inflammatory disease burden. Global experts have identified that, in COVID-19, high concentration of an inflammatory chemokine (MCP-1) in lung fluid is correlated with poor patient outcomes. Therefore, this would be effectively the same mechanism as DMX-200 uses against FSGS and DKD: where active inflammatory processes are driving disease progression, DMX-200 would work to reduce damage from inflammatory immune cells, by blocking their signalling activity, and limiting subsequent movement.

DMX-200 is being prepared for the study at our FDA-approved global contract manufacturer, and we have engaged with regulatory authorities accordingly. We anticipate that first efficacy data for DMX-200 in respiratory complications associated with COVID-19 will be available this financial year.

Historically, pandemics have lasted 12-36 months, and we are unfortunately seeing some resurgences in the current pandemic right now. While COVID-19 is likely to be around for a while yet, if DMX-200 does show benefit in ARDS associated with COVID-19, it may also show benefit in ARDS associated with other infections too, such as pneumonia and influenza. Thus, the ARDS trial could lead to opportunities extending beyond COVID-19.

We were recently awarded $1 million from the Australian Government from the highly competitive Medical Research Future Fund towards our inclusion in the REMAP-CAP study. We view this funding as an endorsement of the strong scientific rationale for DMX-200 in this setting. Dimerix is uniquely positioned to support the global effort in identifying COVID-19 treatments.

DMX-700 in chronic Obstructive Pulmonary Disease (COPD)

Lastly, DMX-700, our therapeutic candidate in COPD, is in pre-clinical testing. DMX-700 for COPD is a very different candidate to DMX-200, targeting a different disease pathway. Our DMX-700 drug candidate has been shown to block Interleukin 8 receptor beta (IL-8Rβ, also known as CXCR2) and angiotensin II receptor type 1 (AT1R) that have been independently implicated in the pathophysiology of COPD.

The DMX-700 development plan will continue to progress towards the clinical phase, with in vivo assessment in an appropriate COPD model to confirm in vitro observations in relevant pre-clinical models of the disease. The components of DMX-700 have a known safety profile in human studies, meaning an accelerated clinical development path can be pursued once in vivo efficacy is demonstrated.

Healthy Cash Position

At 30 June, Dimerix held cash reserves of $7.8 million. The current cash balance provides a solid base for the company's current activities including planning for our proposed global Phase 3 pivotal program in FSGS, as well as for the COVID-19 study in ARDS. We continue to assess the longer-term strategy including planning for the success of DMX-200 and progressing towards submitting an IND application to the FDA, associated partnering activities, DMX-700 development plans, and the impact on future cash flow and funding.

Dimerix has evolved significantly over the past couple of years, and now has multiple assets in commercially attractive and growing markets that all have a high unmet need and with little or no current marketed competition. Our goal is to develop commercially attractive products for unmet medical needs and to create value for our shareholders. I look forward to reporting on our progress and as we meet these key milestones.

Yours faithfully

Dr Nina Webster

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

Authorised for lodgement by the Board of the Company

—END—

About DMX-200
DMX-200 is the adjunct therapy of a chemokine receptor (CCR2) antagonist administered to patients already receiving irbesartan, an angiotensin II type I (AT1) receptor blocker and the standard of care treatment for hypertension and kidney disease. DMX-200 is protected by granted patents in various territories until 2032.

In 2017, Dimerix completed its first Phase 2a study in patients with a range of chronic kidney diseases. No significant adverse safety events were reported, and all study endpoints were achieved. The compelling results from this study prompted the decision to initiate two different clinical studies in 2018: one for patients with Diabetic Kidney Disease; and the second for patients with another form of kidney disease, Focal Segmental Glomerulosclerosis (FSGS). DMX-200 is also under investigation as a potential treatment for acute respiratory distress syndrome (ARDS) in patients with COVID-19.

Diabetic Kidney Disease
There were 23 million diagnosed diabetics in the US alone in 2017, and the incidence of diabetes is estimated to grow by 54% by the year 2040. Approximately 40% of all diabetics suffer from kidney disease, which is a progressive disease leading to kidney failure and dialysis – and many of them do not know it yet. So sadly, has a large – and growing – population. With the incidence of diabetes growing so rapidly globally, so too will the incidence of kidney disease. This is a rapidly growing market, for which there is no cure for DKD, and current treatment options are ineffective as the kidneys deteriorate towards failure. Dimerix reported statistically and clinically significant outcomes in a Phase 2 study in diabetic kidney disease patients in September 2020.

The diabetic kidney disease market is reported to be US$5.8 billion per annum ($8 billion) market, and estimated to grow at 5.1% a year by 2022. We believe our addressable market is at least US$1.1 billion (AU$1.5 billion), a market that is growing as diabetes incidence rises.

FSGS
FSGS is a very rare disease; and a particularly heart-breaking one. FSGS attacks the kidney's filtering units, where blood is cleaned (called the 'glomeruli'), causing irreversible scarring, which 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: sadly, it affects both adults and children as young as two years old. For those who are lucky enough to receive a kidney transplant, approximately 40% will get re-occurring FSGS in the transplanted kidney. At this time, there are no drugs approved for FSGS anywhere in the world, so the treatment options and prognosis are poor. Dimerix reported positive Phase 2a data in FSGS patients in July 2020.

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.

FSGS is a billion-dollar plus market: the number of people with FSGS in the US alone is just over 80,000, and worldwide about 210,000. The illness has a global compound annual growth rate of 8 per cent, with over 5,400 new cases diagnosed in the US alone each year. 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.