For Immediate Release

ASX/Media Release

Dimerix announces outcomes of DMX-200 pre-IND meeting with the FDA

KEY POINTS:

- Path to drug registration in USA of DMX-200 in patients with chronic kidney disease (CKD) confirmed
- Path to the near term milestone of filing IND for the first US study (PK study) – no apparent roadblocks or extra costs identified at this stage
- DMX-200 to be treated as an adjunct therapy rather than a combination therapy – resulting in a much smaller pivotal trial which is less expensive as it requires fewer patients
- Potential for approval from a single pivotal Phase III trial with single end point of improvement in proteinuria from baseline – bringing huge cost benefits over running two Phase III trials
- Recognition of the importance of heterodimer pharmacology – validating the patented Dimerix technology in identifying new treatments

MELBOURNE, Australia, 1st August 2016: Dimerix Limited (ASX: DXB), a clinical-stage biotechnology company committed to discovering and developing new therapeutic treatments identified using its proprietary screening assay, today announced it has received the minutes from the pre-IND meeting held with the US Federal Drug Administration (FDA) on the 29th June 2016. The minutes confirm the positive reception for this new therapeutic and provide a range of important clarifications for the path to registration DMX-200 as a treatment for patients with chronic kidney disease (CKD), specifically, for the orphan indication of Focal Segmental Glomerular Sclerosis (FSGS) in the USA.

DMX-200 was identified using Dimerix's proprietary screening assay, termed Receptor-Heteromer Investigation Technology (Receptor-HIT), and it combines two existing drugs, a chemokine receptor CCR2 blocker (propagermanium) used for its anti-inflammatory properties, and an angiotensin II type I receptor blocker (irbesartan) which is registered in the USA for hypertension and treatment of diabetic nephropathy. Dimerix has already secured orphan designation for DMX-200 for FSGS.

During the pre IND meeting Dimerix confirmed with the FDA that as angiotensin receptor blockers (ARB's), including irbesartan, are standard of care for treatment of chronic kidney diseases, it is appropriate that DMX-200 is positioned as an adjunct therapy and not a fixed dose combination therapy. Dimerix thus plans to package Propagermanium as an extended release formulation, reducing dosage from current three times daily dosing, to be delivered to patients on irbesartan therapy.

The treatment of DMX-200 as an adjunct therapy greatly reduces the complexity of the Phase III trial required for registration, compared with those for a fixed dose combination therapy. Moreover, it provides a relatively simple, and inexpensive, path to opening an IND for a pharmacokinetic (PK) study for the extended release formulation. There were no major roadblocks identified for the near term milestone of opening the IND.

A substantial portion of the meeting was focused on identification of appropriate end points for a pivotal Phase III trial in FSGS. Proteinuria is common in FSGS patients and is broadly accepted as a strong independent risk factor for disease progression. In the minutes from the pre-IND meeting the FDA advised that for DMX-200 *"A substantial change in proteinuria in patients with marked proteinuria at baseline may be an acceptable endpoint for traditional or accelerated approval…"*. Extensive discussion of this point provided Dimerix with vital information to assist in the design of the likely single pivitol Phase III trial required to secure registraion for DMX-200.

The FDA also provided valuable feedback on the ongoing Phase II trial currently underway in Australia that assists Dimerix to maximise the supporting value of this Australian trial to the pivotal Phase III trial.

Dimerix Executive Chairman Dr James Williams said, "The FDA was extremely helpful in providing Dimerix with advice and information to help us succeed in the development of DMX-200 for FSGS. As this rare and severe disease has no current effective treatments, the FDA has shown significant interest in assisting companies to expedite their development path to ensure treatment options are made available to patients as quickly as possible. By opening this dialogue early with the Agency, Dimerix has received guidance as to the type of information that will ultimately be required, de-risking the program significantly and as a consequence, it appears substantial further investment should not be required before filing the IND for the PK study (initial study under US IND). We were also particularly pleased with the recognition of the importance of heterodimer pharmacology in the development of new therapeutic approaches as this encourages us to further leverage our platform into new drug discovery programs."

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Dimerix Bioscience Pty Ltd

Dimerix Limited's wholly owned subsidiary Dimerix Bioscience Pty Ltd is a clinical-stage pharmaceutical company committed to discovering and developing new therapeutic models identified using its proprietary assay, termed Receptor-Heteromer Investigation Technology (Receptor-HIT). This assay enables the identification of pairs of receptors that function in a joint manner (interact) when ligands, small molecule drugs, peptides or antibodies, bind to them. The Receptor-HIT technology was used to identify DMX-200 and an internal drug development program, initially for the treatment of a subset of patients with chronic kidney disease. In addition to its own therapeutic programs, the company also earns revenue by providing this technology to global pharmaceutical firms. For more information see www.dimerix.com

DMX 200

DMX-200 combines two existing drugs, irbesartan and propagermanium. Irbesartan is an off-patent angiotensin II type I receptor blocker indicated for the treatment of hypertension and nephropathy in Type II diabetic patients. Propagermanium (PPG) is a chemokine receptor (CCR2) blocker, which has been used for the treatment of Hepatitis B in Japan and is available in the USA for its anti-inflammatory properties. DMX-200 has been shown to improve the outcome of chronic kidney disease by reducing proteinuria by more than 50 per cent in animal models [(1)].

The DMX-200 Phase II Trial

The trial is a single arm, open label study in adult patients with chronic kidney disease (with proteinuria). The primary end points are the incidence and severity of adverse events and the clinically significant changes in the safety profile of participants. The secondary end points are obtained from statistical analysis of biomarker data at each time point including change from baseline, and the proportion of responders defined as those participants achieving normalisation of proteinuria (proteinuria within normal limits) or those participants achieving a 50 per cent reduction in proteinuria.

The trial has two parts. Part A is a dose escalation trial recruiting up to 30 patients. All patients recruited to the trial will be on stable irbesartan therapy, and will be treated with propagermanium dosed orally three times per day. Each patient will commence on 30mg PPG/day and the dose increased each 28 days to a maximum of 240mg/day, or until proteinuria is absent or reduced to a level the clinician considers acceptable.

The Company expects to carry out an interim analysis of the Part A data to confirm the safety of the therapy and observe any biomarker changes on up to 15 patients. It is expected interim data will be available during 2016.

Part B is an expansion study, in which up to 30 patients will be given the optimal dose identified from Part A.

Chronic Kidney Disease

Chronic kidney disease can result from diabetes, high blood pressure and diseases that cause inflammation specifically in the kidneys. Proteinuria is the most common manifestation of the disease. As the disease progresses it can lead to end-stage renal disease (ESRD) where the kidneys fail. The only treatment for ESRD is a kidney transplant or regular blood-cleansing treatments called dialysis. More than 26 million people suffer from the disease in the United States.

[1] Functional interaction between angiotensin II receptor type 1 and chemokine (C-C motif) receptor 2 with implications for chronic kidney disease.
Ayoub MA, Zhang Y, Kelly RS, See HB, Johnstone EK, McCall EA, **Williams** JH, Kelly DJ, **Pfleger** KD. PLoS One. 2015 Mar 25;10(3):e0119803. doi: 10.1371/journal.pone.0119803.