ASX/Media Release

Sun Biomedical Limited Expands Kidney Disease Study Sites

Melbourne and Perth, Australia, 26 October 2015 - Sun Biomedical Limited (ASX: SBN) is pleased to announce the addition of a fourth site to its Phase II clinical study into the safety and efficacy of a new treatment for kidney disease.

The Melbourne Renal Research Group (MRRG) headed by leading private nephrologist Clinical Associate Professor David Packham will immediately begin recruiting adult patients into the study of DMX-200, an innovative and promising new treatment that combines two different approved drugs to treat chronic kidney disease.

Sun Biomedical will conduct an interim analysis of the primary and secondary endpoints on the first 15 patients, to inform further clinical development in an orphan indication.

Sun Biomedical Limited Executive Chairman Dr James Williams said, "Clinical Associate Professor Packham and MRRG are well known to the pharmaceutical industry for their commitment to clinical research and successful patient recruitment. The addition of this site to the three public sites in Melbourne, in combination with a recently completed review and expansion of the patient inclusion criteria, is expected to support the timely recruitment of patients for the trial."

"It is very exciting to be able to offer my patients an opportunity to trial an innovative new treatment" said Clinical Associate Professor Packham.

Sun Biomedical has published preclinical data showing that combining the two drugs blocks an inflammatory response which prevents the kidneys from functioning properly and releasing protein into the urine, called proteinuria [(1)].

About the Phase II Trial

The trial is a single arm, open label trial 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% 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 by mid 2016.

[(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. eCollection 2015.

Part B is an expansion study, in which up to 30 patients are recruited on the best dose identified from Part A. The Company expects to review the design of Part B in consultation with the FDA and in light of all data available to the Company, prior to commencement of Part B. These discussions will be in line with the company's strategy of pursuing registration for an orphan indication in which the sufferers exhibit chronic kidney disease. Orphan indications of chronic kidney disease include Focal Segmental Glomerulosclerosis (FSGS), Membranous Nephropathy (MN) and Minimal Change Disease (MCD). The trial has commenced at four sites in Melbourne, Australia, and may be expanded into other jurisdictions to meet recruitment targets and regulatory goals.

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.

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 for Hepatitis B. DMX-200 has been shown to improve the outcome of chronic kidney disease by reducing proteinurea by more than 50 per cent in animal models.

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For more information please contact:
James Williams
Executive Chairman
+61 409 050 519

About Dimerix Bioscience Limited

Sun Biomedical Limited's wholly owned subsidiary Dimerix Bioscience Limited is a clinical-stage pharmaceutical company committed to discovering and developing new therapeutic paradigms identified using its proprietary screening 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. Sun Biomedical acquired DMX-200, and the Receptor-HIT technology, through its acquisition of Dimerix Bioscience Limited, which completed in early July 2015.