

DIMERIX HOLDS PRE-IND MEETING ON DMX-200 WITH FDA

MELBOURNE, Australia, 25 November 2019: Dimerix Limited (ASX: DXB), a clinical-stage biopharmaceutical company, today confirmed that the US Food and Drug Administration (FDA) met with Dimerix for a Pre-Investigational New Drug (pre-IND) meeting. At the pre-IND meeting, the FDA reviewed a dossier that summarised Dimerix' proposed Phase 3 clinical program for Focal Segmental Glomerulosclerosis (FSGS) and its supporting data in the form of non-clinical studies, the manufacturing and process controls and existing Phase 1 and Phase 2 clinical data accumulated to date.

Importantly, the meeting provided clarity on the remaining development of DMX-200 for FSGS through to market approval, including confirmation of endpoints for accelerated marketing approval, and the requirement for a single Phase 3 study. The agency also confirmed the proposed non-clinical package and proposed specifications for the pharmaceutical-grade drug manufactured by Dimerix are appropriate for registration of DMX-200.

"This formal meeting with the FDA gave us a valuable opportunity to ensure that the proposed development programs meet with US regulatory expectations for marketing approval. This will build on the numerous constructive discussions we have had with key regulatory agencies worldwide, including previous interactions with the FDA", Dimerix CEO and Managing Director, Dr Nina Webster said. "Following the pre-IND meeting, and upon read-out of the current Phase 2 studies mid calendar year 2020, Dimerix will well be positioned to complete and lodge an IND application for DMX-200 which will include an international Phase 3 study design for FSGS patients".

Focal Segmental Glomerulosclerosis is a serious and rare disease that attacks the kidney's filtering units (glomeruli) causing scarring of the tissues, leading to permanent kidney damage and kidney failure. FSGS affects both children and adults. There are no treatments currently approved for the treatment of FSGS and thus there is a strong unmet medical need.

Dimerix has received Orphan Drug Designation for DMX-200 in both the US and Europe for the treatment of FSGS. Dimerix established with the respective regulatory agencies that "the intention to treat FSGS with DMX-200 was justified based on preliminary non-clinical data which showed a reduction in the number of podocytes lost and an improvement in proteinuria." Furthermore, as stated by the respective regulatory agencies, the orphan designation indicates that "Dimerix has provided sufficient justification that if approved, [DMX-200] is likely to be of significant benefit to those affected by the condition" and that "[DMX-200] would provide a

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clinically relevant advantage as an alternative to any currently marketed products". Orphan designation also provides regulatory and financial benefits to help bring DMX-200 to market in the US and Europe faster, including reduced fees during the product development phase, protocol assistance from the regulatory authorities, and 7-year (US) and 10-year (Europe) market exclusivity following product approval.

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

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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 products DMX-200 for both Diabetic Kidney Disease and Focal Segmental Glomerulosclerosis (FSGS), and DMX-700 for Chronic Obstructive Pulmonary Disease (COPD). DMX-200 and DMX-700 were 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 irbesartan, an angiotensin II type I (AT1) receptor blocker and the standard of care treatment for kidney disease. DMX-200 has 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. In a subsequent sub-group analysis, significant clinical efficacy signals were seen in the diabetic group.

DMX-200 administered to patients already taking irbesartan reduced proteinuria levels by a further 36%. This reduction in proteinuria is highly correlated with improved renal function and delay in kidney failure and dialysis. 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).

FSGS is a serious and rare disease that attacks the kidney's filtering units (glomeruli) causing serious scarring which leads to permanent kidney damage and kidney failure and for which there is a recognised medical need for a new or improved treatment. FSGS affects both children and adults.

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.

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