

DIMERIX TO HOST PROJECT PARASOL WEBINAR ON FSGS BIOMARKER INSIGHTS

Investor Webinar 4 pm AEDT | Wednesday, 6 November 2024

You are invited to register using this link:

https://us06web.zoom.us/webinar/register/WN_3GNk0nwWSY-UhFhIbERCZQ

Participants may submit questions at registration or during the session

MELBOURNE, Australia, 06 November 2024: Dimerix Limited (ASX: DXB) invites you to join an upcoming webinar dedicated to reviewing key initial findings from Project PARASOL, a collaborative international initiative for clinical endpoints in focal segmental glomerulosclerosis (FSGS).

Project PARASOL is focused on defining quantitative relationships between short-term changes in key biomarkers—proteinuria and glomerular filtration rate (GFR)—and long-term outcomes in FSGS. The project's goal is to establish alternative proteinuria-based endpoints to support both accelerated and traditional approval pathways for FSGS treatments.

Dr. Alex Mercer, a member of the PARASOL Organising Committee, will be present to answer questions and provide insights on these latest findings.

We look forward to welcoming both new and existing stakeholders as we further explore advancements in kidney disease research.

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

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About ACTION3 FSGS Phase 3 Study

The Phase 3 study, which is titled “Angiotensin II Type 1 Receptor (AT1R) & Chemokine Receptor 2 (CCR2) Targets for Inflammatory Nephrosis”, or ACTION3 for short, is a pivotal (Phase 3), multi-centre, randomised, double-blind, placebo-controlled study of the efficacy and safety of DMX200 in patients with FSGS who are receiving a stable dose of an angiotensin II receptor blocker (ARB). Once the ARB dose is stable, patients will be randomized to receive either DMX200 (120 mg capsule twice daily) or placebo.

The single Phase 3 trial in FSGS patients has interim analysis points built in that are designed to capture evidence of proteinuria and kidney function (eGFR slope) during the trial, aimed at generating sufficient evidence to support marketing approval.

Further information about the study can be found on ClinicalTrials.gov (Study Identifier: NCT05183646) or Australian New Zealand Clinical Trials Registry (ANZCTR) (Study Identifier ACTRN12622000066785).

About Dimerix

Dimerix (ASX: DXB) is a clinical-stage biopharmaceutical company working to improve the lives of patients with inflammatory diseases, including kidney diseases. Dimerix is currently focused on developing its proprietary Phase 3 product candidate DMX-200 (QYTOVRA® in some territories), for Focal Segmental Glomerulosclerosis (FSGS) kidney disease, and is also developing DMX-700 for respiratory disease. 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.

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, with patent applications submitted globally that may extend patent protection to 2042, in addition to any exclusivity period that may apply in key territories. In 2020, Dimerix completed two Phase 2 studies: one in FSGS and one in diabetic kidney disease, following a successful Phase 2a trial in patients with a range of chronic kidney diseases in 2017. No significant adverse safety events were reported in any trial, and all studies resulted in encouraging data that could provide meaningful clinical outcomes for patients with kidney disease.

About 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.¹ For those who are fortunate enough to receive a kidney transplant, approximately 60% will get re-occurring FSGS in the transplanted kidney.² At this time, there are no drugs specifically approved for FSGS anywhere in the world, so the treatment options and prognosis are limited. FSGS is a billion-dollar plus market: the number of people with FSGS in the US alone is just over 80,000,¹ and worldwide about 220,000.³ The illness has a global compound annual growth rate of 8%, with over 5,400 new cases diagnosed in the US alone each year.⁴ Because there is no effective treatment, Dimerix has received Orphan Drug Designation for DMX 200 in both the US and Europe for FSGS. 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 a fast-tracked regulatory pathway to approval. Dimerix reported positive Phase 2a data in FSGS patients in July 2020.

References

- 1 Guruswamy Sangameswaran KD, Baradhi KM. (2021) *Focal Segmental Glomerulosclerosis*, online: <https://www.ncbi.nlm.nih.gov/books/NBK532272/>
- 2 *Front. Immunol.*, (July 2019) | <https://doi.org/10.3389/fimmu.2019.01669>
- 3 *Delve Insight Market Research Report (2022): Focal segmental glomerulosclerosis (FSGS) – Market Insight, Epidemiology and market forecast – 2032*; <https://www.delveinsight.com/report-store/focal-segmental-glomerulosclerosis-fsgs-market>;
- 4 *Nephcure Kidney International (2020); Focal Segmental Glomerulosclerosis*, online <https://nephcure.org/livingwithkidneydisease/understanding-glomerular-disease/understanding-fsgs/>