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Ã¢â?¬Å?Kidney failure was the third fastest growing cause of death in 2023 exacerbated by the lack of treatments for kidney diseaseÃ¢â?¬Â•

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Dimerix, a clinical-stage biopharmaceutical company, is at the forefront of developing innovative treatments for inflammatory diseases, including kidney and respiratory conditions. With its lead candidate, DMX-200, currently in a pivotal Phase 3 clinical trial for FSGS, the company is making significant strides in advancing therapies for rare and complex diseases. The drug has already earned Orphan Drug Designation from both the US FDA and EMA, and Dimerix has secured strategic licensing deals in Europe, Canada, Australia, New Zealand, and the Middle EastÃ¢â?¬â?•valued at A$350 million in upfront and potential milestone payments, plus royalties. In this interview, Dr Nina Webster, CEO and Managing Director of Dimerix, Australia shares the company's journey, key trends shaping the future of biopharmaceuticals, and Dimerix's next steps in its mission to transform the treatment landscape for rare patients worldwide.



How has the company evolved since its incorporation in 2004 to develop innovative treatments for inflammatory diseases?

Dimerix is a publicly listed, Australian clinical-stage biopharmaceutical company originally founded on a scalable, proprietary platform technology—Receptor-HIT. We are focused on developing products for inflammatory diseases, particularly unmet needs in kidney and respiratory diseases.

Dimerix was initially set up as a fee-for-service company, using its proprietary technology to screen drug candidates for large

pharmaceutical companies. However, using Receptor-HIT, we identified our pipeline opportunities.

Over the last 12 years, Dimerix has focused on developing its promising candidate, DMX-200, to treat kidney disease. Specifically, Dimerix is currently undertaking a randomised, double-blind, multi-centre, placebo-controlled global phase 3 trial of DMX-200 to treat a rare and progressive type of kidney disease called Focal Segmental Glomerulosclerosis (FSGS), for which no approved products exist anywhere in the world.

Can you explain how your proprietary Receptor-HIT technology works and what makes it scalable and adaptable for different drug discovery needs?

Our Receptor-Heteromer Investigation Technology (HIT) platform uses cell-based assays to identify promising drug candidate activity at the receptor level. Receptor-HIT can be applied at several stages of drug development across different joint receptors.

While Dimerix has identified a promising pipeline of potential candidates through Receptor-HIT, we are currently focused on our DMX-200 phase 3 trial aimed at addressing the global unmet need for FSGS treatment.

DMX-200 (QYTOVRA) is in Phase 3 trials for FSGS kidney disease. Could you explain how it works as an adjunct therapy and how it differs from the current standard of care?

FSGS is a rare, progressive and aggressive kidney disease with no current treatment. FSGS has many underlying causes and occurs globally across all age groups, including children as young as two years old.

FSGS patients typically present with high blood pressure. This causes a build-up of pressure in the kidney vessels that causes inflammation. This persistent and ongoing inflammation in turn leads to sclerosis or fibrosis in the kidney, and ultimately the death of kidney cells. The remaining kidney cells come under increasing stress, accelerating the disease and as such, FSGS usually leads to kidney failure in 5-8 years.

FSGS patients typically progress to renal failure, requiring dialysis, and in some cases, where available, kidney transplants. Unfortunately, 60 per cent of such transplants are in turn affected by FSGS.

The current standard of care for FSGS is to treat high blood pressure. Dimerix's DMX-200 candidate is aimed at reducing the inflammation in the kidney and thus preventing scarring and fibrosis. As such, DMX-200 works as an adjunct therapy, given to patients already on the blood pressure medication.

The DMX-200 phase 3 trial is currently recruiting FSGS patients across 19 countries and approximately 170 clinical trial sites. It has a truly global reach. This also means we are engaged with regulators across 19 countries, including key markets in Europe, Asia and North America.

As FSGS is a rare disease, DMX-200 successfully received orphan drug designation in the US, Europe and the UK, and has the potential for breakthrough designation in other territories. As such, while the full trial is a two-year study, we have built in two different interim analysis points. The first interim trial analysis occurred in March 2024 which confirmed the study was on track for its final endpoints. The next interim analysis is planned when the 144th patient reaches week 35, which we expect to occur around mid-2025 based on current recruitment.

What are the company's plans for bringing DMX-200 and other pipeline candidates to global markets? Do you foresee launching these therapies in APAC, and what hurdles do you anticipate?

Given the high unmet need, we aim to get a safe, effective treatment to as many FSGS patients as possible, as soon as possible, wherever they live.

For this reason, we are working with regulatory authorities across 19 countries to ensure our phase 3 DMX-200 trial efficiently and effectively meets varied regulatory requirements to support both recruitment and ultimate marketing approval. We have opened trial sites across Latin America, Europe, Asia, and Australasia.

We anticipate launching DMX-200 across multiple territories including the Asia-Pacific. In Asia, we are currently recruiting patients in Taiwan, Hong Kong, Mainland China and Malaysia. Critically, we have worked with the National Medical Products Administration (NMPA), the Chinese regulatory agency, to enable recruitment directly into our multi-region phase 3 trial.

Our orphan drug status aids our potential for a faster pathway to markets, extended exclusivity periods, as well as enabling orphan drug pricing which recognises the need for commercial incentives to tackle rare diseases.

We have already licensed DMX-200 in Europe, Canada, Australia, New Zealand and the Middle East. Collectively, those deals are valued at around A$350 million in upfront and potential milestone payments plus royalties. However, this is only a part of the global opportunity we are actively pursuing, with a focus on other key markets such as the US and Chinese markets.

While FSGS is a rare disease, approximately 220,000 people across the seven major markets are diagnosed with FSGS each year, through biopsies. Since biopsy is a surgical procedure, this suggests that these patients have access to health care and thus any treatment. While there is nothing on the market for FSGS at this time, a different type of rare kidney disease product launched in 2021 is priced at approximately $10,000 per month per patient, or $120,000 per annum per patient, providing a reference point for rare kidney disease pricing expectations. These costs are typically met by insurers in jurisdictions like the US or public health systems in countries like the UK or Australia.

In terms of hurdles, one of the biggest challenges in rare disease clinical trials is patient recruitment due to the uncommon nature of such diseases. This is why we have opened 170 clinical sites across 19 countries worldwide to recruit for this study.

Beyond DMX-200, are there any new drug candidates or applications for the Receptor-HIT platform that you are particularly excited about?

Dimerix sees its near-term focus and significant opportunity in completing the phase 3 DMX-200 trial and bringing the first specific treatment for FSGS to global markets.

Dimerix is in a strong cash position to continue its global phase 3 trial. Further, we have the near-term potential of the interim analysis outcomes and further potential licensing deals on the horizon. We believe 2025 will be a transformational year for Dimerix.

Our Receptor-HIT platform has identified a raft of potential longer-term opportunities that we will bring into our candidate pipeline at the appropriate time. Dimerix will accelerate promising drug candidates at the right time, including addressing kidney and respiratory inflammation.

Ayesha Siddiqui