QYTOVRA®
[REPAGERMANIUM]

Dimerix

Immediate Release

FDA APPROVES COMMERCIAL BRAND NAME FOR DIMERIX PHASE 3 DRUG CANDIDATE

Highlights

- United States FDA grants conditional approval for commercial brand name, QYTOVRA® (formerly DMX-200) in FSGS
- Full approval would be granted following a successful new drug application
- The trademark has also been registered in Europe, UK, Australia, China, Japan, and Republic of Korea, with applications pending in other key territories, including the USA and Canada
- Commercial scale manufacturing arrangements for QYTOVRA® are well advanced
- Part 1: Last patient data collection for Phase 3 study scheduled for 26 February 2024
- Part 1: First analysis expected to be reported on, or around, 15 March 2024[1]

MELBOURNE, Australia, 25 September 2023: Dimerix Limited (ASX: DXB) a biopharmaceutical company with late-stage clinical assets in inflammatory diseases, today confirmed that the US Food and Drug Administration (FDA) has given conditional approval for the brand name QYTOVRA® (pronounced kai-toe-vra) for its Phase 3 clinical drug candidate (formerly DMX-200) in focal segmental glomerulosclerosis (FSGS). Final approval would be granted following a successful new drug application (NDA).

It is a regulatory requirement that pharmaceutical companies submit new proprietary name applications to the FDA after certain clinical trials are conducted, which is an entirely separate process to trademark applications made with the United States Patent and Trademark Office (USPTO). For drugs offered in the United States, brand names must be reviewed and approved by the FDA before the drug may be marketed and sold. This process can often take at least 12 months, followed by a 6-month FDA review. The main goal of the FDA's review is to ensure patient safety by mitigating the potential for medication errors, in particular any likelihood of confusion between the proposed new drug name and any existing drug names. In so doing, the FDA evaluates whether the proposed drug name looks like or sounds like any other pending or approved names, which also includes handwriting and dialect tests, as well as reviews of reports of medication error data.

The trademark for QYTOVRA® has also been accepted and registered in Europe, UK, Australia, China, Japan, Republic of Korea, with applications pending in USA and Canada. Furthermore, Dimerix also made a formal application to the United States Adopted Names (USAN) Council, which granted QYTOVRA® a USAN designation for repagermanium, and which will appear in the United States Pharmacopeial Convention, Inc. list of International Drug Names.

Dimerix HQ
425 Smith St, Fitzroy 3065
Victoria, Australia
T. 1300 813 321
E. info@dimerix.com

The commercial manufacturing arrangements for QYTOVRA® are a key part of the marketing applications to regulatory authorities. In parallel with the Phase 3 clinical trial, Dimerix has been working closely with its commercial manufacturing partner to produce the required commercial registration batches and associated stability data to support the shelf-life and those regulatory filings.

"As our potential new treatment for this rare kidney disease moves closer to market, the name DMX-200 for FSGS had been replaced by the intended commercial brand name QYTOVRA®.
The potential commercial value of QYTOVRA® continues to increase as we successfully execute on each element of the development program. We have surpassed our first 72 patients randomised into this Phase 3 trial, as we move towards the outcome of Part 1 analysis in March 2024. In parallel, we continue to engage with the FDA, EMA and NMPA as well as prospective marketing partners. We are excited about the prospect of making this unique product available to patients in all major markets and, in doing so, deliver strong financial returns back to Dimerix and its investors."

Dr Nina Webster, CEO & Managing Director, Dimerix Limited

FSGS Phase 3 Study

The Phase 3 study, which is titled **"A**ngiotensin II Type 1 Receptor (AT1R) & **C**hemokine Receptor 2 (CCR2) **T**argets for **I**nflammat**o**ry **N**ephrosis" – or ACTION3 for short, is a pivotal (Phase 3), multi-centre, randomised, double-blind, placebo-controlled study of the efficacy and safety of QYTOVRA® 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 QYTOVRA® (120 mg capsule twice daily) or placebo.

The single Phase 3 trial in FSGS patients has two 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 accelerated marketing approval. A successful outcome in the first analysis, expected on or around 15 March 2024[1], would see the Company announce that, based on available data, the study is on track to see a clinically and statistical meaningful improvement in proteinuria in patients on QYTOVRA® versus placebo and that the trial is continuing to Part 2.

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).

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

Dr Nina Webster
Dimerix Limited
Chief Executive Officer & Managing Director
Tel: +61 1300 813 321
E: investor@dimerix.com

Rudi Michelson
Monsoon Communications
Tel: +61 3 9620 3333
Mob: +61 (0)411 402 737
E: rudim@monsoon.com.au

Follow us on **LinkedIn** and **Twitter**

Authorised for lodgement by the Board of the Company

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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 product QYTOVRA®, for Focal Segmental Glomerulosclerosis (FSGS), and Diabetic Kidney Disease, and is developing DMX-700 for Chronic Obstructive Pulmonary Disease (COPD). QYTOVRA® 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 QYTOVRA®

QYTOVRA® 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. QYTOVRA® is protected by granted patents in various territories until 2032, with patent applications submitted globally that may extend patent protection to 2042.

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.

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.[2] For those who are fortunate enough to receive a kidney transplant, approximately 60% will get re-occurring FSGS in the transplanted kidney.[3] At this time, there are no drugs specifically approved for FSGS anywhere in the world, so the treatment options and prognosis are poor.

FSGS is a billion-dollar plus market: the number of people with FSGS in the US alone is just over 80,000,[2] and worldwide about 220,000.[5] 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 QYTOVRA® 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 *Current independent Data Safety Monitoring Board (DSMB) scheduled meeting*

2 *Guruswamy Sangameswaran KD, Baradhi KM. (2021) Focal Segmental Glomerulosclerosis), online: https://www.ncbi.nlm.nih.gov/books/NBK532272/*

3 *Front. Immunol., (July 2019) | https://doi.org/10.3389/fimmu.2019.01669*

4 *Nephcure Kidney International (2020); Focal Segmental Glomerulosclerosis, online*

5 *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;*