DIMERIX AND TAIBA ENTER INTO AN EXCLUSIVE LICENSE AGREEMENT TO COMMERCIALISE DMX-200 IN THE MIDDLE EAST

Investor Webinar 10.15am AEST Monday 27 May

You are invited to register using this link:
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Participants may submit questions at registration or during the session

- Taiba acquires exclusive rights to register and commercialise DMX-200 for the treatment of Focal Segmental Glomerulosclerosis (FSGS) in the United Arab Emirates (UAE), Saudi Arabia, Oman, Kuwait, Qatar, Bahrain and Iraq
- Taiba's core therapeutic focus is in rare diseases and has extensive experiencing commercialising medicines, being the first company to provide medicines for rare diseases in the Middle East
- Dimerix to receive up to ~AU$120.5 million[1] from Taiba in upfront and milestone payments, in addition to royalties:
    - US$350,000 (~AU$0.5 million[1, 2]) upfront payment
    - Up to US$80.4 million (~AU$120 million[1]) in milestone payments on certain development and sales milestones being achieved
    - Tiered royalties starting at 30% on net sales
- Taiba is the second license deal executed for DMX-200 following the license deal with Advanz Pharma (announced 5 October 2023)[3] and collectively the license deals provide:
    - almost AU$11.5 million[1,3] in upfront payments
    - up to approximately AU$340 million[1,3] in potential milestone payments
    - tiered royalties on net sales
- Dimerix continues to negotiate with potential licensees outside the Taiba and Advanz Pharma territories with a key focus being the major markets of US and China, including on various non-binding term sheets it has received for licensing opportunities
- The Taiba licensing deal follows Dimerix' successful interim analysis for DMX-200 (announced 11 March 2024)

MELBOURNE, Australia, 27 May 2024: Dimerix Limited (ASX: DXB, "**Dimerix"**) and Taiba Middle East FZ LLC, ("**Taiba**"), today announced that they have entered into an exclusive license agreement for the commercialisation of Dimerix' Phase 3 drug candidate DMX-200 for the treatment of focal segmental glomerulosclerosis (FSGS) kidney disease in the United Arab Emirates (UAE), Saudi Arabia, Oman, Kuwait, Qatar, Bahrain and Iraq. Dimerix retains all rights to commercialise DMX-200 in all other unlicensed territories, including the US and China.

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In countries across the Middle East, such as Bahrain, Kuwait, Oman, Qatar, Saudi Arabia and the United Arab Emirates, citizens typically have free, government-sponsored access to healthcare and any treatments that become available for their diseases.[4] Furthermore, across the majority of the Middle East, the prices of an orphan disease drug are commonly set according to either the price in the country of origin or the price of the approved product in the US or Europe.[5] As such, in the case DMX-200 is commercialised with orphan drug status, the price would be expected to be based in line with the US Food and Drug Administration (FDA) or European Medicines Agency (EMA) pricing model.[5]

Established in 1980, Taiba Middle East FZ LLC is a privately owned company and was the first company to provide medicines for rare diseases in the Middle East. Taiba has multiple subsidiary companies, including Taiba Rare LLC and Menagen Pharmaceutical Industries LLC, which focus on marketing and manufacturing therapeutics for rare diseases to the Middle East with a diverse, innovative portfolio and a strong focus on access to health for patients. Taiba's focus and extensive experience in bringing innovative medicines to patients in the Middle East makes them an outstanding partner for Dimerix in the potential commercialisation of DMX-200 in the United Arab Emirates (UAE), Saudi Arabia, Oman, Kuwait, Qatar, Bahrain and Iraq.

"We are thrilled to partner with Dimerix in launching DMX-200 in the Middle East pending FDA approval. DMX-200 will strengthen our portfolio of treatments for rare nephrology diseases, enabling us to offer a comprehensive solution for our treating physicians. Leveraging our existing network, knowledge and expertise, we aim to introduce a breakthrough medication for our patients suffering from focal segmental glomerulosclerosis (FSGS). Our dedication to collaborating with Dimerix underscores our commitment to bringing hope to patients with rare disease conditions such as FSGS."

Dr Saif Al Hasani, CEO, Taiba ME

Dimerix will continue to fund and execute the global ACTION3 Phase 3 study for DMX-200 in FSGS patients, and Taiba will be responsible for submission and maintenance of the regulatory dossier in its licensed territories, as well as all sales and costs of marketing activities. Dimerix will receive an upfront payment of US$350,000[2] (~AU$0.5[1] million) within 30 days. Furthermore, Dimerix is eligible to receive potential payments of up to US$80.4 million (~AU$120[1] million) on certain development and commercialisation milestones being achieved and tiered percentage royalties starting at 30% and decreasing by 5% every 5 years down to 20% on net sales of DMX-200 in the region, if successfully commercialised (all contracted financial terms are denominated in US$).

"We are very pleased to be partnering with the Taiba group for the Middle East. The unique knowledge and expertise that the Taiba team has built in the rare disease space, as well as the established regulatory support and supply chain, places them in the ideal position to achieve the optimum outcome in the Middle East territories for all stakeholders. We very much look forward to collaborating with all our partners, as we all strive to make a difference in kidney diseases, which have such an urgent unmet need."

Dr Nina Webster, CEO & Managing Director, Dimerix

Dimerix and Taiba will form a Joint Steering Committee to align the development and commercialisation of DMX-200 in FSGS in the territories. Taiba also has a right to negotiate a license to develop and commercialize DMX-200 in any additional indications in the licensed territories that Dimerix may achieve for DMX-200. The minimum term is 15 years, or until the last valid patent claim covering the product expires (whichever is the latest). The agreement otherwise contains terms common for an arrangement of this kind, including termination provisions that, amongst other matters, allows for Taiba to terminate on 180 days' notice.

Following on from Dimerix' successful interim analysis of DMX-200 in its global ACTION3 Phase 3 study for FSGS (announcement 11 March 2024), Dimerix now has two high quality partners across multiple territories, providing strong support for Dimerix in advancing and commercialising DMX-200 as a potential new treatment for FSGS. Collectively across both licences, Dimerix may become eligible for an additional up to AU$340 million[1] in milestone payments, in addition to royalties on net sales. Dimerix continues to negotiate the non-binding term sheets received for licensing opportunities with potential partners outside the Taiba (United Arab Emirates (UAE), Saudi Arabia, Oman, Kuwait, Qatar, Bahrain and Iraq) and Advanz Pharma (EEA, Canada, Switzerland, UK, Australia and New Zealand) territories, with a key focus being the major markets of US and China.

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

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Authorised for lodgement with ASX by the Board of Dimerix

-ENDS-

About ACTION3 FSGS CLINICAL STUDY **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 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 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 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 Taiba

Taiba is a leading specialty marketing, sales and distribution company in the MENA region, providing innovative treatments to patients suffering from orphan and rare diseases. Taiba's vision is to cover the unmet medical need in its region providing high quality products and high level of service to healthcare organizations and hospitals and commitment to patient treatment. Taiba's focus is addressing the needs of rare disease patients and providing them access to innovative medicines either through name patients sales or through commercialization.

About Dimerix

Dimerix (ASX: DXB) is a clinical-stage biopharmaceutical company working to improve the lives of patients with inflammatory diseases, including both kidney and respiratory diseases. Dimerix is currently focussed 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 Chronic Obstructive Pulmonary Disease (COPD). DMX-700 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.[6] For those who are fortunate enough to receive a kidney transplant, approximately 60% will get re-occurring

FSGS in the transplanted kidney.[7] 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,[6] and worldwide about 220,000.[8] The illness has a global compound annual growth rate of 8%, with over 5,400 new cases diagnosed in the US alone each year.[9] 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 *Based on exchange rate of 1 US$ = 1.509 AUD as at 27 May 2024*

2 *In the event that EMA or FDA do not approve a marketing authorization within 2 years of a Regulatory Submission, Dimerix shall have the option to either issue to Taiba Dimerix ordinary shares equal to US$350,000 divided by the Share Value or pay the amount of US$350,000 in cash*

3 *ASX release 5 October 2023*

4 *See Taiba Rare Website (2024) online: https://taibarare.com/*

5 *Kanavos, P et al. (2018); Pharmaceutical pricing and reimbursement in the Middle East and North Africa region A mapping of the current landscape and options for the future; London School of Economics and Political Science; available at: https://www.lse.ac.uk/business/consulting/assets/documents/pharmaceutical-pricing-and-reimbursement-in-the-middle-east-and-north-africa-region.pdf*

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

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

8 *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;*

9 *Nephcure Kidney International (2020); Focal Segmental Glomerulosclerosis, online https://nephcure.org/livingwithkidneydisease/understanding-glomerular-disease/understanding-fsgs/*