For Immediate Release

DIMERIX AND ADVANZ PHARMA ENTER INTO AN EXCLUSIVE LICENSE AGREEMENT TO COMMERCIALISE DMX-200 IN EUROPE, CANADA, AUSTRALIA, AND NEW ZEALAND

- ADVANZ PHARMA acquires exclusive rights to register and commercialise DMX-200 for the treatment of Focal Segmental Glomerulosclerosis (FSGS) in the European Economic Area, the UK, Switzerland, Canada, Australia, and New Zealand
- Dimerix to receive up to ~AU$230* million in upfront and milestone payments, plus royalties
    - €6.5 million (~AU$10.8 million*) in upfront payment
    - up to €132 million (~AU$219 million*) in potential milestones
    - tiered royalties on net sales
- Focal Segmental Glomerulosclerosis (FSGS) is a rare disease that causes kidney scarring and can lead to end-stage kidney disease
- DMX-200 is in development in the global ACTION3 Phase 3 clinical trial; first analysis outcome expected to be reported on, or around, 15 March 2024[1]
- ADVANZ PHARMA will leverage its specialty, hospital, and rare disease expertise and commercial platform to register and effectively promote the product and offer greater patient access
- Dimerix retains all rights to DMX-200 in all other territories

MELBOURNE, Australia, 05 October 2023: ADVANZ PHARMA Corp. Limited ("**ADVANZ**") and Dimerix Limited (ASX: DXB, "**Dimerix"**), today announced they have entered into an exclusive license agreement for the European Economic Area, the UK, Switzerland, Canada, Australia, and New Zealand for the commercialisation of Dimerix' Phase 3 drug candidate DMX-200 for the treatment of focal segmental glomerulosclerosis (FSGS) kidney disease, following regulatory approval. Dimerix retains all rights to commercialise DMX-200 outside of these territories. DMX-200 is currently in global Phase 3 clinical development, in which the first analysis outcome is expected in March 2024.

Dimerix will continue to fund and execute the global ACTION3 Phase 3 study for DMX-200 in FSGS patients, and ADVANZ will be responsible for submission and maintenance of the regulatory dossier in the licensed territories, as well as all sales and marketing activities. In exchange for these rights, Dimerix will receive an upfront payment of €6.5 million (~AU$10.8* million) within 30 days, plus potential development and commercialisation milestones of up to €132 million (~AU$219* million). In addition, Dimerix is eligible to receive tiered, escalating, mid-teen to twenty percentage royalties on net sales of DMX-200 if successfully commercialised (all contracted financial terms are denominated in Euros).

"We are excited to announce this partnership with Dimerix, which is fully in line with our strategy to be a partner of choice for the commercialisation of specialty, hospital, and rare disease medicines in Europe, Canada, and Australia. We are committed to bring innovative rare disease medicines to market which serve a high unmet patient need."

Steffen Wagner, CEO, ADVANZ PHARMA

Dimerix and ADVANZ will form a Joint Steering Committee to align the development and commercialisation of DMX-200 in FSGS in the territories. Any data and regulatory filings generated by ADVANZ or Dimerix may be used by either party for the development and commercialization of DMX-200 in their respective territories. ADVANZ has a right of first offer to negotiate a license to develop and commercialize DMX-200 in any additional indications in the licensed territories.

Dimerix continues to pursue and progress licensing opportunities with potential partners outside the ADVANZ territories.

"We are delighted to be partnering with ADVANZ in Europe, UK, Australia, New Zealand and Canada. The ADVANZ team has a proven record in developing and commercialising medicines in areas with no approved therapies and high unmet needs. ADVANZ's expertise and resources will be invaluable in supporting Dimerix to advance our shared goal of commercialising this novel treatment, and this partnership recognises the decade of work by our dedicated team, consultants, trial participants, and investigators in the developing a new therapy for patients with FSGS."

Dr Nina Webster, CEO & Managing Director, Dimerix

"With limited treatment options currently available and many patients who do not adequately respond to existing treatment regimes, there remains a significant unmet need for efficacious FSGS therapies Dimerix' and ADVANZ's commitment to DMX-200 brings us closer to the first potential treatment specifically for FSGS designed to improve the lives of those suffering from the disease".

Professor Jonathan Barratt, Nephrologist, Mayer Professor of Renal Medicine: University of Leicester, Co-Chair UK Glomerulonephritis Clinical Study Group

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

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Authorised for lodgement with ASX by the Board of Dimerix

-ENDS-

About ACTION3 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 ADVANZ

ADVANZ PHARMA is a global pharmaceutical company with the purpose to improve patients' lives by providing the specialty, hospital, and rare disease medicines they depend on. Our headquarters are in London, UK. We have commercial sales in more than 90 countries globally and have a direct commercial presence in more than 20 countries, including key countries in Europe, the US, Canada, and Australia, a Centre of Excellence in Mumbai, India, as well as an established global distribution and commercialisation partner network. ADVANZ PHARMA's product portfolio and pipeline comprises innovative medicines, specialty generics & biosimilars, and originator brands. Our products cover a broad range of therapeutic areas, including hepatology, gastroenterology, anti-infectives, critical care, endocrinology, oncology, CNS, and, more broadly, rare disease medicines. Our ambition is to be a partner of choice for the commercialisation of specialty, hospital, and rare disease medicines in Europe, Canada, and Australia. In line with our ambition, we are partnering with biopharma and development companies to bring medicines to patients. We can only achieve this due to our dedicated and highly qualified employees, acting in line with our company values of entrepreneurship, speed, and integrity.

For more information, please visit ADVANZ PHARMA's website at www.advanzpharma.com.

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.[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 limited.

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.[4] The illness has a global compound annual growth rate of 8%, with over 5,400 new cases diagnosed in the US alone each year.[5] 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

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* *Based on exchange rate of 1 EUR = 1.66034 AUD as at 04 October 2023*

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 *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;*

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