Dimerix and Amicus Therapeutics Announce Exclusive License Agreement for DMX-200 in the United States

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Amicus licenses exclusive U.S. rights to commercialize DMX-200 for the treatment of Focal Segmental Glomerulosclerosis (FSGS)

DMX-200 is in a pivotal Phase 3 trial for FSGS, a rare and fatal kidney disease with no FDA-approved therapies

Dimerix successfully completed Type C meeting with the FDA in March 2025, aligning on proteinuria as the primary endpoint for approval

Dimerix to receive US$30 million (~AU$48 million) upfront payment, up to US$560 million (~AU$892 million) for success-based milestone payments, in addition to tiered royalties on DMX-200 net U.S. sales

MELBOURNE, Australia and PRINCETON, N.J., April 30, 2025 (GLOBE NEWSWIRE) -- Dimerix Limited (ASX: DXB, "Dimerix") and Amicus Therapeutics (Nasdaq: FOLD, "Amicus") today announced that the two companies have entered into an exclusive license agreement for the commercialization of Dimerix' Phase 3 drug candidate DMX-200 for all indications, including FSGS, in the United States (U.S.). Dimerix retains all rights to commercialize DMX-200 in all territories other than those already exclusively licensed.

DMX-200 is a small molecule inhibitor of the chemokine receptor 2 (CCR2) under development in a pivotal Phase 3 study, ACTION3, for the treatment of Focal Segmental Glomerulosclerosis (FSGS) kidney disease. In early 2024, Dimerix reported positive interim results from the ACTION3 trial in FSGS showing DMX-200 was performing better than placebo in reducing proteinuria with no safety concerns to date. Full enrollment of ACTION3 is expected by year-end 2025. An additional blinded interim analysis is planned once the revised primary and secondary endpoints have been pre-specified in the protocol and agreed with the FDA. In a March 2025 Type C meeting, Dimerix successfully aligned with the FDA on proteinuria as an appropriate primary endpoint for traditional marketing approval for DMX-200.

"Amicus is thrilled to enter into this collaboration with Dimerix to bring DMX-200 to patients in the U.S., and we are incredibly impressed by their achievements to date. We look forward to leveraging our regulatory, commercial, medical, and advocacy capabilities to bring this potentially transformative treatment to people living with FSGS in the U.S.," said Bradley Campbell, President and Chief Executive Officer, Amicus Therapeutics. "This licensing agreement represents a major step forward in our strategy to strengthen our portfolio and fully aligns with our mission to develop and deliver transformative medicines for people living with rare diseases."

"We are delighted to partner with Amicus in the United States. The Amicus team has a remarkable history of successfully delivering rare disease medicines to those in need. Their expertise and resources will be crucial to help achieve our mutual objective of commercializing this innovative treatment," said Dr. Nina Webster, CEO and Managing Director of Dimerix. "I'm grateful to the dedicated Dimerix team, trial participants, and investigators for their continued commitment to developing a new therapy for patients with FSGS who currently have a poor prognosis and very limited treatment options."

Dimerix will continue to fund and execute the ACTION3 study, and Amicus will be responsible for submission and maintenance of the regulatory dossier in the United States, as well as all costs of commercialization activities. Additionally, Amicus will have the exclusive rights to develop DMX-200 in other future indications in the United States. Amicus and Dimerix will form a Joint Steering Committee to align the development and commercialization of DMX-200 in FSGS in U.S. The agreement otherwise contains terms common for an arrangement of this kind.

In exchange for these rights, Dimerix will receive a US$30 million (~AU$48 million) upfront payment. The next potential milestone payment is based on positive data from the Phase 3 trial in FSGS. In total, Dimerix is eligible to receive potential success-based development and regulatory milestone payments of up to US$75 million (~AU$119 million) until FDA approval of DMX-200 in FSGS, US$35 million (~AU$56 million) on first sale, commercial sales milestone payments of up to US$410 million (AU$653 million), and tiered royalties from the low-teens to low-twenties percentages of DMX-200 net sales in the U.S. In addition, Dimerix is eligible to receive up to US$40 million (~AU$64 million) in milestone payments for potential future indications. The upfront payment from Amicus will be funded with cash on hand. All contracted financial terms are denominated in U.S. dollars.

Evercore Partners International LLP is acting as exclusive financial advisor to Dimerix, and Cooleys LLP is serving as Dimerix legal advisor. Wilson Sonsini Goodrich & Rosati is serving as Amicus legal advisor.

Authorized for lodgment with ASX by the Board of Dimerix.

About ACTION3 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-center, randomized, double-blind, placebo-controlled study of the efficacy and safety of DMX-200 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 DMX-200 (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 DMX-200

DMX-200 is 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 Orphan Drug Designation granted by the FDA in the United States.

About FSGS

FSGS is a rare, serious kidney disorder characterized by progressive scarring (sclerosis) in parts of the glomeruli—the kidney's filtering units. This scarring leads to proteinuria, progressive loss of kidney function, and often end-stage renal disease. FSGS is increasingly understood to have an inflammatory component, with monocyte and macrophage activation contributing to glomerular injury. In the United States, more than 40,000 people are estimated to be living with FSGS, including both adults and children. There are no therapies specifically approved for FSGS in the U.S., and management relies on non-specific immunosuppressive and supportive therapies. In patients with progressive or treatment-resistant FSGS, the average time from diagnosis to end-stage kidney disease can be as short as five years. Even among those who undergo kidney transplantation, disease recurrence occurs in up to 60% of cases, underscoring the urgent need for new, disease-modifying treatments.

About Dimerix Limited

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, 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. For more information, please visit the company's website at www.dimerix.com and follow on X and LinkedIn.

About Amicus Therapeutics

Amicus Therapeutics (Nasdaq: FOLD) is a global, patient-dedicated biotechnology company focused on discovering, developing and delivering novel high-quality medicines for people living with rare diseases. With extraordinary patient focus, Amicus Therapeutics is committed to advancing and expanding a pipeline of cutting-edge, first- or best-in-class medicines for rare diseases. For more information please visit the company's website at www.amicusrx.com, and follow on X and LinkedIn.

Forward Looking Statement

This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 relating to: the Amicus collaboration and license agreement with Dimerix of DMX-200, the timing of Phase 3 clinical trial evaluating DMX-200; the likelihood of success of such clinical trial; the prospects for FDA approval of DMX-200 for FSGS or other indications; the estimated prevalence of FSGS; the achievement of any milestone and timing of any payments associated with milestones and the success of any efforts to commercialize DMX-200, including any projections of future financial performance or payments. The inclusion of forward-looking statements should not be regarded as a representation by us that any of our plans will be achieved. Any or all of the forward-looking statements in this press release may turn out to be wrong and can be affected by inaccurate assumptions we might make or by known or unknown risks and uncertainties. In addition, all forward-looking statements are subject to other risks detailed in our Annual Report on Form 10-K for the year ended December 31, 2024. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. All forward-looking statements are qualified in their entirety by this cautionary statement, and we undertake no obligation to revise or update this news release to reflect events or circumstances after the date hereof.

DIMERIX CONTACTS:

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

AMICUS CONTACTS:

Investors:
Amicus Therapeutics
Andrew Faughnan
Vice President, Investor Relations
afaughnan@amicusrx.com
+1 (609) 662-3809

Media:
Amicus Therapeutics
Diana Moore
Head of Global Corporate Affairs and Communications
dmoore@amicusrx.com
+1 (609) 662-5079

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