# Chimerix Submits Dordaviprone New Drug Application for Accelerated Approval to U.S. FDA for Patients with Recurrent H3 K27M-Mutant Diffuse Glioma

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**Secures Access of Up To $30 Million to Support Potential Launch Through Silicon Valley Bank Credit Facility**

DURHAM, N.C., Dec. 30, 2024 (GLOBE NEWSWIRE) -- Chimerix (NASDAQ: CMRX), a biopharmaceutical company whose mission it is to develop medicines that meaningfully improve and extend the lives of patients facing deadly diseases, today confirms that the Company has submitted a New Drug Application (NDA) with the U.S. Food and Drug Administration (FDA) seeking accelerated approval for dordaviprone as a treatment for patients with recurrent H3 K27M-mutant diffuse glioma in the United States.

“This NDA submission marks a pivotal moment for Chimerix in our mission to bring this potentially life-altering drug to patients diagnosed with recurrent H3 K27M-mutant diffuse glioma,” said Mike Andriole, Chief Executive Officer of Chimerix. “With this submission, we now turn our attention to preparing for potential commercial launch in the U.S. next year. To maximize availability and access of dordaviprone at launch, we have enhanced our commercial capabilities across multiple functions including market access, distribution, reimbursement, patient services, marketing and commercial operations, all supported by a robust manufacturing and quality management system.”

“We also entered into a credit facility of up to $30 million with Silicon Valley Bank providing access to additional capital during this upcoming investment cycle and helping ensure dordaviprone availability to as many patients as possible, as quickly as possible, if approved. We are grateful to our partners at Silicon Valley Bank for their long-term support of Chimerix. This credit facility provides valuable financial optionality leading up to, and through, a potential U.S. launch of dordaviprone,” said Michelle LaSpaluto, Chief Financial Officer of Chimerix.

Chimerix has requested Priority Review for the NDA. If granted, the resulting six-month FDA review period is expected to result in a potential Prescription Drug User Fee Act (PDUFA) action date in the third quarter of 2025. Dordaviprone has received Rare Pediatric Disease Designation for H3 K27M-mutant glioma and has applied for a Rare Pediatric Disease PRV as part of this NDA submission.

In addition, the Company announced it entered into an amended and restated loan and security agreement for up to $30 million with Silicon Valley Bank (SVB), a division of First-Citizens Bank. Under the terms of the agreement, Chimerix may draw down up to $20.0 million through the period ending February 28, 2026. An additional $10 million may also be made available upon the Company’s request through February 28, 2027, subject to SVB’s approval. No draws have been made on this facility to date.

**About Chimerix**
Chimerix is a biopharmaceutical company with a mission to develop medicines that meaningfully improve and extend the lives of patients facing deadly diseases. The Company’s most advanced clinical-stage development program, dordaviprone, is in development for H3 K27M-mutant glioma. The Company is conducting Phase 1 dose escalation studies of ONC206 to evaluate safety and PK data.

**About Dordaviprone**
Dordaviprone (ONC201) is a novel first-in-class small molecule imipridone that selectively targets the mitochondrial protease ClpP and dopamine receptor D2 (DRD2).

**Forward-Looking Statements**
This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that are subject to risks and uncertainties that could cause actual results to differ materially from those projected. Forward-looking statements include those relating to, among other things: the availability and use of any future borrowings under the credit facility; the possible regulatory path forward for dordaviprone, including the timing and consequences of accelerated approval, Priority Review, rare pediatric disease Priority Review vouchers and approval for marketing authorization; FDA’s acceptance for filings; the timeline of related discussions with the FDA; the initial potential PDUFA timing; the timing of the U.S. commercial launch; the ability of dordaviprone to attain significant market acceptance among disease experts, patient advocates and their patients; and the expected impact of dordaviprone on patients. Among the factors and risks that could cause actual results to differ materially from those indicated in the forward-looking statements are: risks related to the availability and use of any future borrowings under the credit facility; risks related to the ability to obtain and maintain accelerated approval, Priority Review, rare pediatric disease Priority Review vouchers, and approval for marketing authorization; uncertainty on the response of regulators to including additional supportive data to be submitted in the NDA filing, including RANO 2.0 assessments, and uncertainty with respect to the initial potential PDUFA timing; risks related to the timing, completion and outcome of the Phase 3 ACTION study of dordaviprone; risks associated with market acceptance; risks associated with repeating positive results obtained in prior preclinical or clinical studies in future studies; risks related to the clinical development of our clinical candidates; and additional risks set forth in the Company’s filings with the Securities and Exchange Commission. These forward-looking statements represent the Company's judgment as of the date of this release. The Company disclaims, however, any intent or obligation to update these forward-looking statements.

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