Chimerix to Submit Dordaviprone for Accelerated Approval to U.S. FDA for Patients with Recurrent H3 K27M-Mutant Diffuse Glioma Before Year-End

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Potential Approval in Q3 2025 in Recurrent H3 K27M-Mutant Diffuse Glioma

Submission Plan Follows Productive and Collaborative Pre-NDA Interactions with FDA

Company to Host Conference Call on Tuesday, December 10 at 8:30 AM ET

DURHAM, N.C., Dec. 09, 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 announced that, following extensive dialogue with the U.S. Food and Drug Administration (FDA), the Company plans to submit a complete New Drug Application (NDA) seeking accelerated approval for dordaviprone as a treatment for recurrent H3 K27M-mutant diffuse glioma in the United States before year-end.

“We expect that, if approved, dordaviprone will fundamentally change the treatment landscape for patients suffering from this lethal form of brain cancer who have extremely limited treatment options. We have worked collaboratively with the U.S. FDA, disease experts and patient advocates throughout the year to potentially accelerate access to dordaviprone for this patient community,” said Mike Andriole, Chief Executive Officer of Chimerix. “In anticipation of a potential approval, we have bolstered our commercial leadership team and will be ready for a U.S. launch as early as the third quarter of 2025, pending application acceptance and Priority Review, if granted.”

“As a pediatric oncologist, this program is particularly meaningful given the impact a potential approval would have on children and young adults devastated by this disease. We are confident that the data generated to date could support an accelerated approval for this urgent unmet medical need,” said Allen Melemed M.D., Chief Medical Officer of Chimerix. “H3 K27M mutant gliomas are extremely aggressive and affect over 2,000 patients annually in the United States. If successful, dordaviprone would be the first FDA-approved therapy for this lethal disease, as well as one of the first molecularly defined approvals for any high-grade glioma.”

The following recent program milestones and additional supportive data were extensively discussed with the FDA and will be included in the NDA:

- Substantial enrollment of the Phase 3 ACTION study
- Phase 2 objective response rate of the 50-patient primary efficacy analysis assessed by blinded independent central review (BICR) as the primary basis of efficacy in the NDA
- Several response assessments, including the most contemporary response assessment criteria for gliomas, Response Assessment in Neuro-Oncology 2.0 (RANO 2.0), under which dordaviprone demonstrated an objective response rate of 28%, a median duration of response of 10.4 months and a median time to response of 4.6 months
- Additional clinical data sets and patient narratives supportive of the primary efficacy analysis
- Clinical and nonclinical demonstration of dordaviprone-driven reversal of the central hallmark of H3 K27M-mutant glioma, H3K27 trimethyl loss
- Comprehensive safety database of glioma patients and healthy volunteers that supports a favorable benefit/risk profile
- Comprehensive clinical pharmacology and chemistry, manufacturing, and controls (CMC) studies

Chimerix will request Priority Review for the NDA. If granted, the resulting six-month FDA review period is expected to result in a potential initial 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 is eligible to apply for a Rare Pediatric Disease Priority Review Voucher (PRV). Chimerix intends to apply for a Rare Pediatric Disease PRV in the upcoming NDA submission.

Conference Call and Webcast
Chimerix will host a conference call and live audio webcast on Tuesday, December 10 at 8:30 a.m. ET. To access the live conference call, please dial 646-307-1963 (domestic) or 800-715-9871 (international) at least five minutes prior to the start time and refer to conference ID 8870160. A live audio webcast of the call will also be available on the Investors section of Chimerix’s website, www.chimerix.com. An archived webcast will be available on the Chimerix website approximately two hours after the event.

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 possible regulatory path forward for dordaviprone, including the potential to seek accelerated approval, Priority Review, rare pediatric disease Priority Review vouchers and approval for marketing authorization; timing and consequences of an NDA submission to FDA; FDA's acceptance for filings; the timeline of related discussions with the FDA; the initial potential PDUFA timing; the potential commercial opportunity; 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 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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