Chimerix Announces Updated Phase 2 Response Assessment of Dordaviprone in Recurrent H3 K27M Glioma at the 2024 SNO Meeting

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DURHAM, N.C., Nov. 11, 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 upcoming presentations at the 2024 Society for Neuro-Oncology (SNO) Annual Meeting, which will be held in Houston, TX from November 21 – 24, 2024.

“We are excited to provide an updated assessment of objective response to dordaviprone previously reported in the blinded independent central review (BICR) cohort[1] in recurrent H3 K27M-mutant diffuse midline glioma using Response Assessment in Neuro-Oncology (RANO) 2.0[2], the most recently established criteria for this disease. This analysis demonstrates an overall response rate of 28.0%, a median time to response of 4.6 months plus a median duration of response of 10.4 months,” said Allen Melemed, MD, Chief Medical Officer at Chimerix. We expect to include the updated RANO 2.0 results in our planned upcoming New Drug Application to Australian regulators.”

“RANO 2.0 is a recently established response assessment criteria for gliomas that supersedes prior versions such as RANO-HGG and RANO-LGG. RANO 2.0 incorporates an integrated quantitative assessment of both enhancing and non-enhancing disease that were not adequately assessed by prior criteria. In addition, it includes minor responses, which in certain regions of the brain, such as midline structures, have disproportionate clinical benefit. This benefit often includes meaningful improvement in neurological symptoms and quality of life outcomes,” said Patrick Y. Wen, MD, Director of the Center for Neuro-Oncology at Dana-Farber Cancer Institute.

Details for the RANO 2.0 presentation as well as other pipeline presentations at SNO are as follows:

Title: Response by RANO 2.0 criteria in ONC201 (dordaviprone)-treated patients with recurrent H3 K27M-mutant diffuse midline glioma
Abstract Code: CTNI-54
Session Date and Time: Friday, November 22, 2024, from 7:30-9:30 PM
Location: The George R. Brown Convention Center, Hall B3

Title: Allosteric mitochondrial ClpP agonist ONC206 alters stress response, metabolic and epigenetic profiles to elicit anti-cancer efficacy in high-grade gliomas
Abstract Code: EXTH-37
Session Date and Time: Friday, November 22, 2024, from 7:30-9:30 PM
Location: The George R. Brown Convention Center, Hall B3

Title: Safety of ONC201 treatment in patients with previously treated H3 K27M-mutant glioma: results from ONC028, an ongoing compassionate use program
Abstract Code: NCOG-07
Abstract Session: CNS Rare Tumors
Presentation Date and Time: Saturday, November 23, 2024, from 10:45am-12:15pm

Title: Early reduction in MRI diffusion apparent diffusion coefficient (ADC) strongly predicts long term response to ONC201 therapy in patient with H3K27M-DMG
Abstract Code: NIMG-29
Abstract Session: Pediatrics II
Presentation Date and Time: Saturday, November 23, 2024, from 10:45am-12:15pm

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, ONC201, is in development for H3 K27M-mutant glioma.

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, expectations regarding interim OS data from the ACTION study, plans for Provisional Registration and commercialization in Australia, expectations regarding assessment of responses. 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, uncertainty on the response of regulators to including RANO 2.0 assessments in an application for marketing authorization; risks related to the timing, completion and outcome of the Phase 3 ACTION study of ONC201; 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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1. Arrillaga-Romany, et al, Journal of Clinical Oncology, Feb 2024
2. Wen, et al, Journal of Clinical Oncology, Sept 2023

Source: Chimerix, Inc.