# Chimerix Reports Second Quarter 2024 Financial Results and Provides Operational Update

August 13, 2024 at 7:00 AM EDT

*– Phase 3 ACTION Study On-Track; First Interim Overall Survival Data Expected Third Quarter 2025 –*

*– ONC206 Phase 1 PK and Safety Data Demonstrate Dose Proportional Exposure with No Dose Limiting Toxicity to Date –*

*– Dordaviprone Filed for Provisional Determination with Therapeutic Goods Administration in Australia –*

*– Conference Call at 8:30 a.m. ET Today –*

DURHAM, N.C., Aug. 13, 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 reported financial results for the second quarter ended June 30, 2024 and provided an operational update.

“We continued our strong execution of the Phase 3 ACTION study and expect the first interim overall survival (OS) data in the third quarter of 2025. As we approach this important milestone, we continue to strengthen our U.S. launch capabilities and readiness,” said Mike Andriole, Chief Executive Officer of Chimerix. “Additionally, we are making great strides advancing ONC206 through the remaining dose cohorts in two Phase 1 trials, which recently achieved dosing within an expected therapeutic range. As we escalate and intensify the dose within this range, we are encouraged by ongoing pharmacokinetic (PK) data that is in line with modeled expectations for delivering dose proportionate exposures for extended durations. Importantly, these exposures have not been associated with dose limiting toxicities thus far. We expect to complete enrollment in the ONC206 dose escalation trials by the end of this year.”

“We have also made progress expanding the global reach for dordaviprone with the recent filing of a Provisional Determination application in Australia. This marks the second of three steps to potential Provisional Approval. Our team continues to be driven by the urgent need of patients focusing on indications where the unmet medical need remains frustratingly high. We will continue to drive our pipeline forward in order to accelerate access to patients in need of new treatment alternatives,” added Mr. Andriole.

**Dordaviprone (ONC201)**

Dordaviprone, a first-in-class imipridone, has the potential to be the first treatment approved for H3 K27M-mutant diffuse glioma. It is an oral small molecule that crosses the blood-brain barrier and selectively binds to the mitochondrial protease ClpP and the G-protein-coupled dopamine receptor D2 (DRD2). Dordaviprone's unique mechanism of action includes alterations of key epigenetic modifications such as reversal of H3 K27me3-loss (H3 K27 trimethyl loss), which is the hallmark of H3 K27M-mutant gliomas.

The Company estimates that approximately 2,000 patients with diffuse glioma harbor the H3 K27M mutation in the United States and approximately 5,000 patients in the top seven markets globally. With no approved therapies specific to this patient population, the standard of care following upfront radiotherapy remains palliative in nature.

Dordaviprone is being evaluated in the Phase 3 ACTION trial that is currently enrolling H3 K27M-mutant diffuse glioma patients at over 140 sites in 13 countries. Chimerix expects interim OS data in the third quarter of 2025. For more information on the ACTION trial, please visit clinicaltrials.gov

Earlier this year, Chimerix initiated the evaluation process for dordaviprone to be considered for Provisional Registration in Australia. The Provisional Registration process is a three-step process which begins with a Pre-Submission Meeting evaluating current data, as well as other program features, including the status of pivotal studies. Chimerix recently initiated the second of three steps in the process, the filing of a Provisional Determination application. Should the TGA approve the Provisional Determination application, the final step is to apply for Provisional Registration. Should Chimerix proceed to the Provisional Registration step, it is expected that a filing could occur as early as year-end 2024 with possible commercial availability in 2026.

**ONC206**

The imipridone ONC206 is a second generation ClpP agonist and DRD2 antagonist which also crosses the blood-brain barrier and is 10x more potent in vitro than dordaviprone. It has demonstrated monotherapy in vivo anti-cancer activity in central nervous system (CNS) tumor models, as well as in vivo solid tumors models outside of the CNS. The two Phase 1 dose escalation trials conducted in partnership with the Pacific Pediatric Neuro-Oncology Consortium (PNOC) and the National Institutes of Health (NIH) have enrolled over 75 pediatric and adult patients with unselected CNS tumors. The dose escalation studies have reached dose level 10 (of 11 planned levels) at 150mg twice per day for three consecutive days, with no dose limiting toxicity observed to date.

The safety profile of ONC206 has been consistent across both pediatric and adult populations, with the majority of treatment-related adverse events being mild to moderate, including fatigue, lymphocyte count decrease and vomiting. No significant change in the overall safety profile has been reported to date as dosing has escalated and intensified in frequency from once per week to twice per day on three consecutive days per week. Completion of enrollment in the remaining two planned dose escalation cohorts is expected to occur in 2024.

Assessment of objective responses in patients where a monotherapy treatment effect can be reliably evaluated is ongoing in dose cohorts at or above target exposure thresholds. The company expects to assess any objective responses in the first half of 2025, allowing sufficient time for response

onset and confirmation in current and future dose cohorts.

Additionally, ONC206 nonclinical studies remain ongoing to identify candidate oncology indications and biomarkers to inform future development plans.

**Second Quarter 2024 Financial Results**

Chimerix reported a net loss of $20.7 million, or $0.23 per basic and diluted share, for the second quarter of 2024. During the same period in 2023, Chimerix recorded a net loss of $18.6 million, or $0.21 per basic and diluted share.

Research and development expenses increased to $18.4 million for the second quarter of 2024, compared to $16.9 million for the same period in 2023.

General and administrative expenses increased to $4.5 million for the second quarter of 2024, compared to $4.4 million for the same period in 2023.

Chimerix's balance sheet at June 30, 2024 included $171.5 million of capital available to fund operations, approximately 89.6 million outstanding shares of common stock and no outstanding debt.

**Upcoming Events**

The Company expects to participate in the 2024 Wedbush PacGrow Healthcare Conference occurring August 13-14, 2024 and the H.C. Wainwright 26th Annual Global Investment Conference taking place September 9-11,2024.

**Conference Call and Webcast**
Chimerix will host a conference call and live audio webcast to discuss second quarter 2024 financial results and provide a business update today 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 5436125. 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 (ONC201), is in development for H3 K27M-mutant diffuse glioma. The Company is conducting Phase 1 dose escalation studies of ONC206 to evaluate safety and PK data.

**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 in Australia, expectations regarding completion of enrollment and assessment of responses in the ONC206 dose escalation trials, and the characteristics and development of ONC206. 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; 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 ONC206; 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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**CHIMERIX, INC.**
**CONSOLIDATED BALANCE SHEETS**
**(in thousands, except share and per share data)**
**(unaudited)**

| | June 30, 2024 | December 31, 2023 |
|---|---|---|
| **ASSETS** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 15,658 | $ 27,661 |
| Short-term investments, available-for-sale | 132,511 | 155,174 |
| Accounts receivable | 129 | 4 |
| Prepaid expenses and other current assets | 5,157 | 6,271 |
| Total current assets | 153,455 | 189,110 |
| Long-term investments | 23,315 | 21,657 |
| Property and equipment, net of accumulated depreciation | 276 | 224 |
| Operating lease right-of-use assets | 1,223 | 1,482 |
| Other long-term assets | 242 | 301 |

| | | |
|---|---|---|
| Total assets | $ 178,511 | $ 212,774 |
| **LIABILITIES AND STOCKHOLDERS' EQUITY** | | |
| Current liabilities: | | |
| Accounts payable | $ 4,163 | $ 2,851 |
| Accrued liabilities | 17,939 | 15,592 |
| Total current liabilities | 22,102 | 18,443 |
| Line of credit commitment fee | - | 125 |
| Lease-related obligations | 827 | 1,177 |
| Total liabilities | 22,929 | 19,745 |
| Stockholders' equity: | | |
| Preferred stock, $0.001 par value, 10,000,000 shares authorized at June 30, 2024 and December 31, 2023; no shares issued and outstanding as of June 30, 2024 and December 31, 2023; no shares issued and outstanding as of June 30, 2024 and | - | - |
| Common stock, $0.001 par value, 200,000,000 shares authorized at June 30, 2024 and December 31, 2023; 89,632,385 and 88,929,300 shares issued and outstanding as of June 30, 2024 and December 31, 2023, respectively | 90 | 89 |
| Additional paid-in capital | 993,778 | 988,457 |
| Accumulated other comprehensive (loss) gain, net | (208) | 7 |
| Accumulated deficit | (838,078) | (795,524) |
| Total stockholders' equity | 155,582 | 193,029 |
| Total liabilities and stockholders' equity | $ 178,511 | $ 212,774 |

**CHIMERIX, INC.**
**CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS**
**(in thousands, except share and per share data)**
**(unaudited)**

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | **2024** | **2023** | **2024** | **2023** |
| **Revenues:** | | | | |
| Contract and grant revenue | $ 129 | $ 26 | $ 129 | $ 260 |
| Licensing revenue | - | - | - | 49 |
| Total revenues | 129 | 26 | 129 | 309 |
| **Operating expenses:** | | | | |
| Research and development | 18,428 | 16,926 | 37,272 | 35,748 |
| General and administrative | 4,533 | 4,448 | 10,079 | 10,127 |
| Total operating expenses | 22,961 | 21,374 | 47,351 | 45,875 |
| Loss from operations | (22,832) | (21,348) | (47,222) | (45,566) |
| **Other income:** | | | | |
| Interest income and other, net | 2,147 | 2,772 | 4,668 | 5,618 |
| **Net loss** | (20,685) | (18,576) | (42,554) | (39,948) |
| **Other comprehensive loss:** | | | | |
| Unrealized loss on debt investments, net | (30) | (582) | (215) | (476) |
| Comprehensive loss | $ (20,715) | $ (19,158) | $ (42,769) | $ (40,424) |
| **Per share information:** | | | | |
| Net loss, basic and diluted | $ (0.23) | $ (0.21) | $ (0.48) | $ (0.45) |
| Weighted-average shares outstanding, basic and diluted | 89,630,959 | 88,583,567 | 89,445,033 | 88,439,894 |

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Source: Chimerix, Inc.