Chimerix Reports Third Quarter 2024 Financial Results and Provides Operational Update

November 7, 2024 at 7:00 AM EST

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

– IDMC Recommends Continuing Conduct of ACTION Study As-Is Following Preplanned Safety Review –

– Alignment with TGA to Submit Dordaviprone for Provisional Approval in Australia –

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

DURHAM, N.C., Nov. 07, 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 third quarter ended September 30, 2024 and provided an operational update.

“We have sustained execution of the Phase 3 ACTION study and continue to be encouraged by the safety profile of dordaviprone following the Independent Data Monitoring Committee’s (IDMC) preplanned safety review which recommended continuing study conduct as-is, including at the more intense twice per week dose. Additionally, the Therapeutic Goods Administration (TGA) has granted orphan drug designation to dordaviprone, and we have alignment to file a New Drug Application (NDA) for Provisional Approval in Australia which we expect to occur in the coming months,” said Mike Andriole, Chief Executive Officer of Chimerix. “As we complete the dordaviprone NDA and look toward the balance of the year, we also expect to complete enrollment in a Phase 1 dose escalation study of ONC206 as we consider future development scenarios for this program.”

“In addition, we were delighted to announce the promotion of Dr. Josh Allen to the role of Chief Scientific Officer this quarter. Josh has been instrumental in the discovery and development of the imipridone class of compounds and expect his broad expertise in cancer biology and strong business acumen will underpin Chimerix early phase development for years to come,” 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 dopamine receptor D2 (DRD2). Dordaviprone's unique mechanism of action includes alterations of key epigenetic modifications such as reversal of H3 K27me3-loss which is the hallmark of H3 K27M-mutant gliomas.

Dordaviprone is being evaluated in the Phase 3 ACTION trial that is currently enrolling H3 K27M-mutant diffuse glioma patients at over 145 sites in 15 countries. Chimerix expects interim OS data in the third quarter of 2025. For more information on the ACTION trial, please visit www.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. The second step, the Provisional Determination Application, was approved during the third quarter 2024, as was the application for Orphan Drug Designation in Australia. The final step is the NDA submission for Provisional Registration which is expected to occur in the coming months with potential commercial availability as soon as year-end 2025.

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 anti-cancer activity in vivo 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 80 pediatric and adult patients with unselected CNS tumors, 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 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.

Corporate

In September 2024, Chimerix promoted Joshua E. Allen, PhD, to the role of Chief Scientific Officer after previously serving as Chief Technology Officer. Dr. Allen co-discovered the anti-cancer activity of ONC201 and co-invented the imipridone class of compounds. He has continuously advanced

the research and development of dordaviprone from academic discovery to its registration program, along with the creation and clinical introduction of biologically distinct derivatives. He received his Ph.D. in Biochemistry and Molecular Biophysics from the University of Pennsylvania. Several research publications, patents, grants, and awards reflect his scientific and entrepreneurial efforts in oncology, including recognition on the Forbes 30 under 30 list. Prior to joining Chimerix, Dr. Allen served as Chief Scientific Officer at Oncoceutics.

Third Quarter 2024 Financial Results

Chimerix reported a net loss of $22.9 million, or $0.26 per basic and diluted share, for the third quarter of 2024. During the same period in 2023, Chimerix recorded a net loss of $24.0 million, or $0.27 per basic and diluted share.

Research and development expenses increased to $19.6 million for the third quarter of 2024 compared to $17.4 million for the same period in 2023.

General and administrative expenses decreased to $5.2 million for the third quarter of 2024 compared to $9.3 million for the same period in 2023. This decrease is due to a one-time non-cash expense related to historical equity grants recognized during the 2023 period.

Chimerix's balance sheet at September 30, 2024 included $152.4 million of capital available to fund operations, approximately 89.9 million outstanding shares of common stock and no outstanding debt.

Conference Call and Webcast

Chimerix will host a conference call and live audio webcast to discuss third 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 6580777. 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 and commercialization 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 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.

CONTACT:

Will O'Connor
Stern Investor Relations
212-362-1200
will@sternir.com

CHIMERIX, INC.
CONSOLIDATED BALANCE SHEETS
(in thousands, except share and per share data)
(unaudited)

	September 30, 2024	December 31, 2023
ASSETS		
Current assets:		
Cash and cash equivalents	$ 23,645	$ 27,661
Short-term investments, available-for-sale	112,585	155,174
Accounts receivable	155	4
Prepaid expenses and other current assets	4,517	6,271
Total current assets	140,902	189,110
Long-term investments	16,201	21,657
Property and equipment, net of accumulated depreciation	281	224
Operating lease right-of-use assets	1,089	1,482
Other long-term assets	195	301
Total assets	$ 158,668	$ 212,774

LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 5,340	$ 2,851
Accrued liabilities	16,904	15,592
Total current liabilities	22,244	18,443
Line of credit commitment fee	-	125
Lease-related obligations	644	1,177
Total liabilities	22,888	19,745
Stockholders' equity:		
Preferred stock, $0.001 par value, 10,000,000 shares authorized at September 30, 2024 and December 31, 2023; no shares issued and outstanding as of September 30, 2024 and December 31, 2023; no shares issued and outstanding as of September 30, 2024 and	-	-
Common stock, $0.001 par value, 200,000,000 shares authorized at September 30, 2024 and December 31, 2023; 89,936,053 and 88,929,300 shares issued and outstanding as of September 30, 2024 and December 31, 2023, respectively	90	89
Additional paid-in capital	996,389	988,457
Accumulated other comprehensive gain, net	258	7
Accumulated deficit	(860,957)	(795,524)
Total stockholders' equity	135,780	193,029
Total liabilities and stockholders' equity	$ 158,668	$ 212,774

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Revenues:				
Contract and grant revenue	$ 26	$ 11	$ 155	$ 271
Licensing revenue	-	-	-	49
Total revenues	26	11	155	320
Operating expenses:				
Research and development	19,646	17,396	56,918	53,144
General and administrative	5,173	9,304	15,252	19,431
Total operating expenses	24,819	26,700	72,170	72,575
Loss from operations	(24,793)	(26,689)	(72,015)	(72,255)
Other income:				
Interest income and other, net	1,914	2,703	6,582	8,321
Net loss	(22,879)	(23,986)	(65,433)	(63,934)
Other comprehensive loss:				
Unrealized gain (loss) on debt investments, net	466	188	251	(288)
Comprehensive loss	$ (22,413)	$ (23,798)	$ (65,182)	$ (64,222)
Per share information:				
Net loss, basic and diluted	$ (0.26)	$ (0.27)	$ (0.73)	$ (0.72)
Weighted-average shares outstanding, basic and diluted	89,701,117	88,620,666	89,531,017	88,500,813

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Source: Chimerix, Inc.