Chimerix Reports Fourth Quarter and Year End 2023 Financial Results and Provides Operational Update

February 29, 2024 at 7:00 AM EST

– ONC201 ACTION Study Progressing; Reiterate Interim OS Data Expected in 2025, Final OS Data Expected in 2026 –

– Phase 2 ONC201 Data Published in Peer-Reviewed Journal of Clinical Oncology –

– $204 Million in Cash and Equivalents at December 31, 2023 –

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

DURHAM, N.C., Feb. 29, 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 fourth quarter and full-year ended December 31, 2023 and provided an operational update.

“Following strong clinical development in 2023, we remain very focused on advancing the ONC201 ACTION study, completing ONC206 dose escalation this year and strengthening our executive team as we prepare for potential commercialization of ONC201,” said Mike Andriole, Chief Executive Officer of Chimerix. “We are making good progress enrolling our global Phase 3 ACTION study and are excited about the prospect of having interim overall survival data next year. In addition, we are pleased to share that the ONC201 Phase 2 data was recently published in the Journal of Clinical Oncology which further elucidates key characteristics of response and detailed patient-level data.”

“During the fourth quarter, we were delighted to strengthen our Board of Directors with the addition of Lisa Decker, Ph.D., as well as strengthen the management team with the promotion of Michelle LaSpaluto to Chief Financial Officer and the additions of Tom Riga as Chief Operating and Commercial Officer and Pablo Lee, MD, as Vice President of Medical Affairs. We are confident their collective expertise will be invaluable assets to Chimerix as we seek to maximize our future growth potential for patients and shareholders,” added Mr. Andriole.

ONC201

Journal of Clinical Oncology Publication

In February 2024, “ONC201 (dordaviprone) in Recurrent H3 K27M-mutant Diffuse Midline Glioma,” was published in the Journal of Clinical Oncology (JCO), a peer reviewed journal of the American Society of Clinical Oncology (ASCO). The manuscript reports in detail the results of 50 patients with recurrent H3 K27M-DMG treated with monotherapy ONC201 who were evaluable for objective response by Response Assessment in Neuro-Oncology (RANO) high grade glioma (HGG) criteria. ONC201 demonstrated a median overall survival (mOS) of 13.7 months (95% CI: 8.0 - 20.3), with an overall two-year rate of survival of 35% (95% CI: 21-49) from the start of ONC201 treatment post-recurrence. Chimerix previously conducted a natural disease history study (n=43) in the recurrent setting evaluating patients who did not receive ONC201 which showed a mOS of 5.1 months (95% CI: 3.9 - 7.7) with an overall two-year survival rate of 11% (95% CI:3.3-24.2).The top-line data from this JCO publication were previously disclosed by Chimerix. The journal can be accessed here.

The Phase 3 ACTION trial is currently enrolling patients at over 130 sites in 13 countries. The trial enrolls patients shortly after completion of front-line radiation therapy that is the standard of care. The study is designed to enroll 450 patients randomized 1:1:1 to receive ONC201 at one of two dosing frequencies or placebo. Participants are randomized to receive 625mg of ONC201 once per week (the Phase 2 dosing regimen), 625mg twice per week on two consecutive days or placebo. The dose will be scaled by body weight for patients <52.5kg. For more information, please visit clinicaltrials.gov

ONC206

ONC206 is a second generation ClpP agonist and DRD2 antagonist that has demonstrated monotherapy anti-cancer activity in pre-clinical models in primary CNS tumors and solid tumors outside of the CNS. Phase I dose escalation trials continue at the National Institutes of Health (NIH) and the Pacific Pediatric Neuro-Oncology Consortium (PNOC) in adult and pediatric CNS tumor patients, respectively. To date, ONC206 has been generally well tolerated with no dose limiting toxicities. The dose escalation trials are currently dosing at more frequent dose schedules, which are expected to increase the duration of therapeutic exposure. Chimerix expects to report preliminary safety and pharmacokinetic data from these trials beginning in mid-2024.

Fourth Quarter 2023 Financial Results

Chimerix’s balance sheet at December 31, 2023 included $204.5 million of capital available to fund operations, no debt, and approximately 88.9 million outstanding shares of common stock.

Chimerix reported a net loss of $18.2 million, or $0.20 per basic and diluted share, for the fourth quarter of 2023, compared to a net loss of $21.0 million, or $0.24 per basic and diluted share for the fourth quarter of 2022.

Research and development expenses decreased to $15.6 million for the three-month period ended December 31, 2023, compared to $19.3 million for the same period in 2022. This decrease was primarily driven by one-time costs associated with a reduction in force related to the TEMBEXA

divestiture in the comparable 2022 period.

General and administrative expenses decreased to $5.2 million for the fourth quarter of 2023, compared to $5.3 million for the same period in 2022.

Full Year 2023 Financial Results

Chimerix reported a net loss of $82.1 million, or $0.93 per basic and diluted share, for the year ended December 31, 2023. For the year ended December 31, 2022, Chimerix recorded net income of $172.2 million, or $1.97 per basic and $1.94 per diluted share. The decrease was primarily driven by the gain on sale of TEMBEXA to Emergent BioSolutions in 2022.

Revenues for 2023 decreased to $0.3 million, compared to $33.8 million in 2022. The decrease was primarily related to deliveries under international TEMBEXA procurement agreements in the comparable 2022 period.

Research and development expenses decreased to $68.8 million for the year ended December 31, 2023, compared to $71.6 million for the year ended December 31, 2022.

General and administrative expenses increased to $24.6 million for the year ended December 31, 2023, compared to $22.1 million for the year ended December 31, 2022.

Conference Call and Webcast
Chimerix will host a conference call and live audio webcast to discuss fourth quarter and full-year 2023 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 6933453. 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, 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, enrollment and timing of data for the Phase 3 ACTION study, the results of dose escalation trials of ONC206, and the impact of recent changes to the Board of Directors and management team. 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 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)

	December 31, 2023	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 27,661	$ 25,842
Short-term investments, available-for-sale	155,174	191,492
Accounts receivable	4	1,040
Prepaid expenses and other current assets	6,271	9,764
Total current assets	189,110	228,138
Long-term investments	21,657	48,626
Property and equipment, net of accumulated depreciation	224	227
Operating lease right-of-use assets	1,482	1,964
Other long-term assets	301	386
Total assets	$ 212,774	$ 279,341
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		

Accounts payable	$ 2,851	$ 3,034
Accrued liabilities	15,592	17,381
Total current liabilities	18,443	20,415
Loan Fees	125	250
Lease-related obligations	1,177	1,819
Total liabilities	19,745	22,484
Stockholders' equity:		
Preferred stock, $0.001 par value, 10,000,000 shares authorized at December 31, 2023 and 2022; no shares issued and outstanding as of December 31, 2023 and 2022	-	-
Common stock, $0.001 par value, 200,000,000 shares authorized at December 31, 2023 and 2022; 88,929,300 and 88,054,127 shares issued and outstanding as of December 31, 2023 and 2022, respectively	89	88
Additional paid-in capital	988,457	970,535
Accumulated other comprehensive gain (loss), net	7	(337)
Accumulated deficit	(795,524)	(713,429)
Total stockholders' equity	193,029	256,857
Total liabilities and stockholders' equity	$ 212,774	$ 279,341

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

	Three Months Ended December 31,		Years Ended December 31,	
	2023	**2022**	**2023**	**2022**
Revenues:				
Procurement revenue	$ -	$ -	$ -	$ 31,971
Contract and grant revenue	4	439	275	942
Licensing revenue	-	-	49	536
Royalty revenue	-	375	-	375
Total revenues	4	814	324	33,824
Cost of goods sold	-	-	-	447
Gross Profit	4	814	324	33,377
Operating expenses:				
Research and development	15,644	19,281	68,788	71,631
General and administrative	5,170	5,347	24,601	22,132
Total operating expenses	20,814	24,628	93,389	93,763
Loss from operations	(20,810)	(23,814)	(93,065)	(60,386)
Other income:				
Interest income and other, net	2,649	2,737	10,970	2,919
Gain on sale of business, net	-	-	-	229,670
(Loss) income before income taxes	(18,161)	(21,077)	(82,095)	172,203
Income tax expense	-	(117)	-	36
Net (loss) income	(18,161)	(20,960)	(82,095)	172,167
Other comprehensive income (loss):				
Unrealized income (loss) on investments, net	632	(300)	344	(316)
Comprehensive (loss) income	$ (17,529)	$ (21,260)	$ (81,751)	$ 171,851
Per share information:				
Net (loss) income, basic	$ (0.20)	$ (0.24)	$ (0.93)	$ 1.97
Net (loss) income, diluted	$ (0.20)	$ (0.24)	$ (0.93)	$ 1.94
Weighted-average shares outstanding, basic	88,910,300	88,049,138	88,604,026	87,555,110
Weighted-average shares outstanding, diluted	88,910,300	88,049,138	88,604,026	88,776,147

Source: Chimerix, Inc.