Chimerix Reports Second Quarter 2023 Financial Results and Provides Operational Update

August 3, 2023 at 7:00 AM EDT

– Phase 3 ACTION Study Ongoing with 77 Sites Activated Across 11 Countries; Reiterate First Interim Overall Survival Analysis Expected Early 2025 –

– ONC206 Dose Escalation Completion Expected in First Half 2024 –

– Capital Available to Fund Operations is $233 Million as of June 30, 2023 –

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

DURHAM, N.C., Aug. 03, 2023 (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, 2023 and provided an operational update.

"I am thrilled to begin leading the organization during such a pivotal time in Chimerix's history and in the field of neuro-oncology, where several genetically defined programs have advanced the field recently. During the second quarter, our team has been laser focused on site activation and enrollment of the Phase 3 ACTION study which now includes 77 sites enrolling patients across 11 countries and an enrollment rate that remains on track for the first interim overall survival analysis in early 2025. We are incredibly grateful to the neuro-oncology community which is eagerly supporting the ACTION study in order to advance the treatment for patients with this cancer. H3 K27M-mutant glioma is estimated to occur in 5,000 people annually in the major global markets," said Mike Andriole, Chief Executive Officer of Chimerix.

"Furthermore, dose escalation for our second-generation compound, ONC206, continues and completion is expected in the first half of 2024. There have been no dose limiting toxicities identified during dose escalation thus far and we are now exploring a more intense dose and schedule with the goal of identifying additional signals of activity," added Mr. Andriole.

ONC201 for Treatment of H3 K27M-Mutant Diffuse Glioma

The Phase 3 ACTION trial is currently enrolling patients at 77 sites in 11 countries and remains on track to report interim data in early 2025.

The ACTION trial is enrolling patients shortly after they have completed standard of care front-line radiation therapy. The study is designed to enroll 450 patients randomized 1:1:1 to receive ONC201 at one of two dosing frequencies or placebo. Participants will be 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. Overall survival (OS) will be assessed for efficacy at three alpha-allocated timepoints: two interim assessments by the Independent Data Monitoring Committee (IDMC) at 164 events and 246 events, respectively, and a final assessment at 327 events. The final progression-free survival (PFS) analysis will be performed after 286 events, with progression assessed using RANO HGG criteria by blinded independent central review (BICR). Secondary endpoints include corticosteroid response, performance status response, change from baseline in quality of life (QoL) assessments and change from baseline in neurologic function as assessed by the Neurologic Assessment in Neuro-Oncology (NANO) scale.

ONC206

ONC206 is a second generation DRD2 antagonist and ClpP agonist that has demonstrated monotherapy anti-cancer activity in pre-clinical models. Phase I dose escalation trials continue at the National Institutes of Health (NIH) and the Pacific Pediatric Neuro-Oncology Consortium (PNOC). In March 2023, the Company reported an investigator-assessed response in a patient with recurrent glioblastoma without the H3K27M-mutation. The patient has continued to respond and remains on treatment, receiving increasing doses as part of the dose escalation. To date, ONC206 is generally well tolerated with a similar safety profile in adults and pediatrics. No dose limiting toxicities have been identified to date. The dose escalation trials are transitioning to intensify dosing from a once weekly dosing to a more frequent dose schedule to increase the duration of therapeutic exposure.

Second Quarter 2023 Financial Results

Chimerix reported a net loss of $18.6 million, or $0.21 per basic and diluted share, for the second quarter of 2023. During the same period in 2022, Chimerix recorded a net loss of $23.5 million, or $0.27 per basic and diluted share.

Research and development expenses decreased to $16.9 million for the second quarter of 2023, compared to $18.0 million for the same period in 2022.

General and administrative expenses decreased to $4.4 million for the second quarter of 2023, compared to $5.8 million for the same period in 2022.

Chimerix's balance sheet at June 30, 2023 included $233.0 million of capital available to fund operations, approximately 88.6 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 second quarter 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 8015897. 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, the probability of success of the Phase 3 ACTION study, the potential filing and approval of an NDA for ONC201 and subsequent commercial opportunity, the implications of the monotherapy radiographic partial response observed during ONC206 dose escalation, the ability to reproduce clinical and pre-clinical findings, and projections regarding funding and timing of future data readouts. 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.

CONTACTS:

Michelle LaSpaluto
919 972-7115
ir@chimerix.com

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)

	June 30, 2023	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 20,099	$ 25,842
Short-term investments, available-for-sale	185,657	191,492
Accounts receivable	26	1,040
Prepaid expenses and other current assets	5,735	9,764
Total current assets	211,517	228,138
Long-term investments	27,258	48,626
Property and equipment, net of accumulated depreciation	256	227
Operating lease right-of-use assets	1,728	1,964
Other long-term assets	326	386
Total assets	$ 241,085	$ 279,341
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,823	$ 3,034
Accrued liabilities	13,518	17,381
Total current liabilities	15,341	20,415
Line of credit commitment fee	125	250
Lease-related obligations	1,507	1,819
Total liabilities	16,973	22,484
Stockholders' equity:		
Preferred stock, $0.001 par value, 10,000,000 shares authorized at June 30, 2023 and December 31, 2022; no shares issued and outstanding as of June 30, 2023 and December 31, 2022	-	-
Common stock, $0.001 par value, 200,000,000 shares authorized at June 30, 2023 and December 31, 2022; 88,583,567 and 88,054,127 shares issued and outstanding as of		

June 30, 2023 and December 31, 2022, respectively	89	88
Additional paid-in capital	978,213	970,535
Accumulated other comprehensive loss, net	(813)	(337)
Accumulated deficit	(753,377)	(713,429)
Total stockholders' equity	224,112	256,857
Total liabilities and stockholders' equity	$ 241,085	$ 279,341

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,	
	2023	**2022**	**2023**	**2022**
Revenues:				
Contract and grant revenue	$ 26	$ -	$ 260	$ -
Licensing revenue	-	440	49	455
Total revenues	26	440	309	455
Cost of goods sold	-	-	-	114
Gross Profit	26	440	309	341
Operating expenses:				
Research and development	16,926	18,047	35,748	37,087
General and administrative	4,448	5,840	10,127	11,472
Total operating expenses	21,374	23,887	45,875	48,559
Loss from operations	(21,348)	(23,447)	(45,566)	(48,218)
Other income (loss):				
Interest income and other, net	2,772	(21)	5,618	(17)
Net loss	(18,576)	(23,468)	(39,948)	(48,235)
Other comprehensive loss:				
Unrealized (loss) gain on debt investments, net	(582)	5	(476)	(47)
Comprehensive loss	$ (19,158)	$ (23,463)	$ (40,424)	$ (48,282)
Per share information:				
Net loss, basic and diluted	$ (0.21)	$ (0.27)	$ (0.45)	$ (0.55)
Weighted-average shares outstanding, basic and diluted	88,583,567	87,436,180	88,439,894	87,263,452

Source: Chimerix, Inc.