Chimerix Reports Fourth Quarter and Year End 2022 Financial Results and Provides Operational Update

March 2, 2023

- Continued Execution and Progress Towards Commercial Approval of Dordaviprone (ONC201) with Global Launch of Phase 3 ACTION Study –

– Confirmed Response in Non-H3 K27M Recurrent Glioblastoma Patient During ONC206 Dose Escalation –

– Strong Balance Sheet with $266 Million in Cash at Year-End and No Debt –

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

DURHAM, N.C., March 02, 2023 (GLOBE NEWSWIRE) -- Chimerix (NASDAQ:CMRX), a biopharmaceutical company whose mission 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, 2022 and provided an operational update.

“We exited 2022 with a clear focus on our oncology pipeline and the initiation of the Phase 3 ACTION trial of ONC201 in patients with H3 K27M-mutant glioma. Patients with this deadly disease are in desperate need of therapeutic options and ONC201’s robust foundation of data underscores its potential as a highly differentiated asset. Following the monetization of TEMBEXA, we have a strong balance sheet to fully fund Chimerix into 2027, including through potential approval of ONC201. Recent independent analyses reported overall survival advantage in patients treated with ONC201, which has further reinforced our confidence in the ACTION trial and the commercial opportunity for ONC201,” said Mike Sherman, Chief Executive Officer of Chimerix.

“As we look to 2023, we are making tremendous progress and continuing our strong execution to advance ONC201 towards regulatory approval. The ACTION trial is enrolling with sites active in the U.S. and internationally, and we remain on track for our first data readout in early 2025 with final data readout expected in 2026. We continue to evaluate emerging data from our earlier pipeline, including ONC206, which recently demonstrated a radiographic tumor response in its dose escalation study,” continued Mr. Sherman.

“The Pacific Pediatric Neuro-oncology Consortium has been pleased to take a leadership role in the clinical development of ONC206,” said Sabine Mueller, MD, PhD, MAS, Professor of Neurology, Neurosurgery and Pediatrics, University of California San Francisco (UCSF) and clinical lead of the Diffuse Midline Glioma Center in Zurich Switzerland. “We are very excited about the potential for ONC206 to treat brain cancers more broadly, beyond those with the H3K27M-mutation. To observe a monotherapy response in a recurrent glioblastoma patient without the H3K27M-mutation is quite exciting. The fact that this occurred with a dose level at the low end of the range has added to our enthusiasm as we continue to dose escalate.”

ONC201 for Treatment of H3 K27M-Mutant Diffuse Glioma

In November 2022, Chimerix initiated the Phase 3 ACTION study, a randomized, double-blind, placebo-controlled, multicenter international study of ONC201 in newly diagnosed diffuse glioma patients whose tumor harbors an H3 K27M-mutation. Treatment with ONC201 will begin shortly after completion of 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 pediatric patients. 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 analysis will be performed after 286 events, with progression assessed using RANO HGG criteria by blinded independent central review (BICR).

Ongoing Development of ONC206

ONC206 is a second generation imipridone that has demonstrated anti-cancer activity in pre-clinical models of various central nervous system (CNS) tumors and other malignancies. ONC206 is a ClpP agonist and DRD2 antagonist with enhanced in vitro potency relative to ONC201. ONC206 is currently being evaluated in Phase 1 dose escalation clinical trials for adults with recurrent primary central nervous system tumors at the National Institutes of Health (NIH) and in pediatric CNS tumors with the Pacific Pediatric Neuro-Oncology Consortium (PNOC). Preclinical and early clinical observations in initial low dose cohorts suggest that ONC206 may be effective for CNS tumors beyond those that harbor the H3 K27M mutation addressed by ONC201.

An investigator- assessed response in a recurrent glioblastoma patient without the H3K27M-mutation who received monotherapy ONC206 has emerged during dose escalation in the PNOC study.

The unmet need in glioblastoma is extraordinarily high with over 25,000 newly diagnosed patients in the United States and Europe annually. Dose escalation will continue, and results are expected to be reported at a future scientific conference.

Fourth Quarter 2022 Financial Results

Chimerix's balance sheet at December 31, 2022 included $266.0 million of capital available to fund operations, no debt, and approximately 88.1 million outstanding shares of common stock.

Chimerix reported a net loss of $21.0 million, or $0.24 per basic and diluted share, for the fourth quarter of 2022, compared to a net loss of $39.5 million, or $0.45 per basic and diluted share for the fourth quarter of 2021.

Research and development expenses decreased to $19.3 million for the three-month period ended December 31, 2022, compared to $34.3 million for the same period in 2021.

General and administrative expenses increased to $5.3 million for the fourth quarter of 2022, compared to $5.2 million for the same period in 2021.

Full Year 2022 Financial Results

Chimerix reported a net income of $172.2 million, or $1.97 per basic and $1.94 per diluted share, for the year ended December 31, 2022. For the year ended December 31, 2021, Chimerix recorded a net loss of $173.2 million, or $2.04 per basic and diluted share. The increase was primarily driven by the sale of TEMBEXA to Emergent BioSolutions.

Revenues for 2022 increased to $33.8 million, compared to $2.0 million in 2021.

Research and development expenses decreased to $71.6 million for the year ended December 31, 2022, compared to $73.8 million for the year ended December 31, 2021.

General and administrative expenses increased to $22.1 million for the year ended December 31, 2022, compared to $18.7 million for the year ended December 31, 2021.

Conference Call and Webcast

Chimerix will host a conference call and live audio webcast to discuss fourth quarter and full-year 2022 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 9730865.

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 approval of and commercial opportunity for ONC201, the implications of the monotherapy radiographic partial response observed during ONC206 dose escalation, and projections regarding funding and 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 the availability of accelerated approval for ONC201; 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, 2022	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 25,842	$ 15,397

Short-term investments, available-for-sale	191,492	72,970
Accounts receivable	1,040	-
Inventories	-	2,760
Prepaid expenses and other current assets	9,764	4,678
Total current assets	228,138	95,805
Long-term investments	48,626	2,022
Property and equipment, net of accumulated depreciation	227	253
Operating lease right-of-use assets	1,964	2,404
Other long-term assets	386	56
Total assets	$ 279,341	$ 100,540
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 3,034	$ 2,788
Accrued liabilities	17,381	13,108
Note payable	-	14,000
Total current liabilities	20,415	29,896
Loan Fees	250	-
Lease-related obligations	1,819	2,392
Total liabilities	22,484	32,288
Stockholders' equity:		
Preferred stock, $0.001 par value, 10,000,000 shares authorized at December 31, 2022 and 2021; no shares issued and outstanding as of December 31, 2022 and 2021	-	-
Common stock, $0.001 par value, 200,000,000 shares authorized at December 31, 2022 and 2021; 88,054,127 and 86,884,266 shares issued and outstanding as of December 31, 2022 and 2021, respectively	88	87
Additional paid-in capital	970,535	953,782
Accumulated other comprehensive loss, net	(337)	(21)
Accumulated deficit	(713,429)	(885,596)
Total stockholders' equity	256,857	68,252
Total liabilities and stockholders' equity	$ 279,341	$ 100,540

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,	
	2022	2021	2022	2021
Revenues:				
Procurement revenue	$ -	$ -	$ 31,971	$ -
Contract and grant revenue	439	-	942	1,928
Licensing revenue	-	46	536	51
Royalty revenue	375	-	375	-
Total revenues	814	46	33,824	1,979
Cost of goods sold	-	-	447	-
Gross Profit	814	46	33,377	1,979
Operating expenses:				
Research and development	19,281	34,337	71,631	73,817
General and administrative	5,347	5,241	22,132	18,672
Acquired in-process research and development	-	-	-	82,890
Total operating expenses	24,628	39,578	93,763	175,379
Loss from operations	(23,814)	(39,532)	(60,386)	(173,400)
Other (loss) income:				
Interest income and other, net	2,737	34	2,919	164
Gain on sale of business, net	-	-	229,670	-
(Loss) income before income taxes	(21,077)	(39,498)	172,203	(173,236)

Income tax expense	(117)	-	36	-
Net (loss) income	(20,960)	(39,498)	172,167	(173,236)
Other comprehensive (loss) income:				
Unrealized loss on investments, net	(300)	(21)	(316)	(21)
Comprehensive (loss) income	$ (21,260)	$ (39,519)	$ 171,851	$ (173,257)
Per share information:				
Net (loss) income, basic	$ (0.24)	$ (0.45)	$ 1.97	$ (2.04)
Net (loss) income, diluted	$ (0.24)	$ (0.45)	$ 1.94	$ (2.04)
Weighted-average shares outstanding, basic	88,049,138	86,867,070	87,555,110	84,930,255
Weighted-average shares outstanding, diluted	88,049,138	86,867,070	88,776,147	84,930,255

Source: Chimerix, Inc.