Chimerix Reports First Quarter 2023 Financial Results and Provides Operational Update

May 4, 2023

– European Union Study Authorization for Phase 3 ACTION Received, Reiterate First Efficacy Data Expected Early 2025 –

– Completion of ONC206 Dose Escalation Expected by First Half 2024 –

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

DURHAM, N.C., May 04, 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 first quarter ended March 31, 2023 and provided an operational update.

“2023 is off to a strong start and has been highlighted by multiple presentations of data in support of our imipridone platform during the recent American Association for Cancer Research Annual Meeting (AACR) and our sponsorship at the Canadian Neuro-Oncology Meeting (CNO) this week,” said Mike Sherman, Chief Executive Officer of Chimerix. “Dr. Carl Koschmann’s ONC201 presentation at AACR marks the first known example of any therapy reversing the H3 K27 trimethyl loss (H3 K27me3-loss) seen in H3 K27M-mutant glioma patients. This shows that dordaviprone (ONC201) can reverse the epigenetic signature which is thought to be a defining characteristic of the disease. Recent literature suggests that reversing the H3 K27M mutation that increases H3 K27 trimethylation in established tumor models results in significant antitumor effects and prolongation of survival. This finding provides additional objective evidence of ONC201 biological activity in this patient population to complement the tumor response observed in the Phase 2 clinical studies. We have also recently completed multiple clinical pharmacology studies, the findings of which have been consistent with our expectations. These studies comprise key elements of a future new drug application (NDA) for ONC201 following positive data from the ACTION study. Our focus has been on accelerating every aspect possible of the Phase 3 ACTION study in order to expedite patient access to this potentially life-altering drug. To that end, we have now received authorization for the ACTION study from nine countries including the United States, the United Kingdom, South Korea, Israel and key markets across Western Europe, as our ramp of site activations continues."

“In addition, we are making good progress advancing the Phase 1 dose escalation studies for our second generation compound, ONC206. As these are open-label studies, in addition to the previously announced objective response observed to ONC206 monotherapy, we hope to identify additional signals of activity this year and look forward to completing dose escalation by first half of 2024,” added Mr. Sherman.

ONC201 for Treatment of H3 K27M-Mutant Diffuse Glioma

In April, Chimerix and along with collaborators presented multiple datasets related to the imipridone platform at the AACR Annual Meeting in Orlando, FL. Key results presented by collaborators at the University of Michigan demonstrated that H3 K27M-mutant glioma patients treated with ONC201 experienced a statistically significant reversal of the H3 K27me3-loss epigenetic signature throughout their tumor compared to patients who did not receive ONC201. Gliomas with the H3 K27M-mutation undergo H3 K27me3-loss, which is a negative prognostic variable among gliomas and thought to be a defining characteristic of the disease. Concordant findings were also reported in preclinical models that were mechanistically linked to specific metabolic changes induced in tumors by ONC201.

Ongoing Development of ONC206

ONC206 is a second generation, potentially differentiated imipridone DRD2 antagonist and ClpP agonist, that has demonstrated monotherapy anti-cancer activity in pre-clinical models. ONC206 is currently being evaluated in Phase I dose escalation trials enrolling patients with advanced central nervous system tumors. In March 2023, the Company reported an investigator-assessed response that emerged during dose escalation in the PNOC study. The responder is a patient with recurrent glioblastoma without the H3K27M-mutation who received ONC206 monotherapy.

Preclinical work is ongoing that is designed to further elucidate the ONC206 mechanism of action, identify potential pharmacodynamic biomarkers, and assess the monotherapy efficacy profile of ONC206 in tumors that do not harbor the H3K27M mutation. These activities will inform data-driven clinical development plans.

First Quarter 2023 Financial Results

Chimerix reported a net loss of $21.4 million, or $0.24 per basic and diluted share, for the first quarter of 2023. During the same period in 2022, Chimerix recorded a net loss of $24.8 million, or $0.28 per basic and diluted share.

Research and development expenses decreased to $18.8 million for the first quarter of 2023, compared to $19.0 million for the same period in 2022.

General and administrative expenses increased to $5.7 million for the first quarter of 2023, compared to $5.6 million for the same period in 2022.

Chimerix's balance sheet at March 31, 2023 included $246.1 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 first 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 8594205.

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 the Phase 3 ACTION Study

The ACTION study is a worldwide, randomized, double-blind, placebo-controlled, multicenter study of ONC201 designed to enroll 450 newly diagnosed diffuse glioma patients whose tumor harbors an H3 K27M-mutation. Treatment with ONC201 begins shortly after completion of radiation therapy. Participants are randomized 1:1:1 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 is 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).

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 and 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.

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

	March 31, 2023	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 15,951	$ 25,842
Short-term investments, available-for-sale	198,801	191,492
Accounts receivable	668	1,040
Prepaid expenses and other current assets	9,330	9,764
Total current assets	224,750	228,138
Long-term investments	31,322	48,626
Property and equipment, net of accumulated depreciation	267	227
Operating lease right-of-use assets	1,848	1,964
Other long-term assets	346	386
Total assets	$ 258,533	$ 279,341
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,847	$ 3,034
Accrued liabilities	13,584	17,381

Total current liabilities	16,431	20,415
Loan Fees	125	250
Lease-related obligations	1,666	1,819
Total liabilities	18,222	22,484
Stockholders' equity:		
Preferred stock, $0.001 par value, 10,000,000 shares authorized at March 31, 2023 and December 31, 2022; no shares issued and outstanding as of March 31, 2023 and December 31, 2022; no shares issued and outstanding as of March 31, 2023 and	-	-
Common stock, $0.001 par value, 200,000,000 shares authorized at March 31, 2023 and December 31, 2022; 88,583,567 and 88,054,127 shares issued and outstanding as of March 31, 2023 and December 31, 2022, respectively	89	88
Additional paid-in capital	975,254	970,535
Accumulated other comprehensive loss, net	(231)	(337)
Accumulated deficit	(734,801)	(713,429)
Total stockholders' equity	240,311	256,857
Total liabilities and stockholders' equity	$ 258,533	$ 279,341

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

	Three Months Ended March 31,	
	2023	**2022**
Revenues:		
Contract and grant revenue	$ 234	$ -
Licensing revenue	49	15
Total revenues	283	15
Cost of goods sold	-	114
Gross Profit	283	(99)
Operating expenses:		
Research and development	18,822	19,040
General and administrative	5,679	5,632
Total operating expenses	24,501	24,672
Loss from operations	(24,218)	(24,771)
Other income:		
Interest income and other, net	2,846	4
Net loss	(21,372)	(24,767)
Other comprehensive loss:		
Unrealized gain (loss) on debt investments, net	106	(52)
Comprehensive loss	$ (21,266)	$ (24,819)
Per share information:		
Net income (loss), basic and diluted	$ (0.24)	$ (0.28)
Weighted-average shares outstanding, basic and diluted	88,294,624	87,088,804

Source: Chimerix, Inc.