Chimerix Reports First Quarter 2024 Financial Results and Provides Operational Update

May 1, 2024 at 7:00 AM EDT

– Dordaviprone (ONC201) ACTION Study Progressing; Reiterates Expectations for Interim Overall Survival (OS) Data in 2025 and Final OS Data in 2026 –

– No Dose Limiting Toxicity in ONC206 Phase 1 Studies to Date, Preliminary Phase 1 Safety and Pharmacokinetic (PK) Data Expected This Summer –

– Company to Advance Dordaviprone in Provisional Registration Process Following Positive Interaction with Therapeutic Goods Administration (TGA) in Australia –

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

DURHAM, N.C., May 01, 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 first quarter ended March 31, 2024 and provided an operational update.

“Patients, caregivers and physicians are in desperate need for novel therapies that offer clinical benefit in H3 K27M-mutant diffuse glioma, and we believe that dordaviprone (ONC201) has the potential to be a major therapeutic advance in the treatment of this disease,” said Mike Andriole, Chief Executive Officer of Chimerix.

“We remain intensely focused on completion of the ACTION study and will continue to be active and collaborative with regulators to bring dordaviprone to patients in need as soon as possible. In parallel, we are continuously evaluating options to accelerate access to dordaviprone in select markets where accelerated regulatory pathways exist as there are few treatment options for this ultra-rare disease beyond radiation therapy. As an example, our recent interaction with the Therapeutic Goods Administration (TGA) in Australia is a positive initial step that is aligned to this overall strategy. Having a pivotal Phase 3 study well underway is an important consideration in global regulatory conversations that contemplate accelerated approval, and the ongoing maturation of the ACTION study enables these conversations,” added Mr. Andriole.

“Furthermore, we continue to progress our second generation imipridone, ONC206, in Phase 1 dose escalation and are enthusiastic about the differentiated profile and activity seen with this molecule thus far. We expect to pursue novel development opportunities apart from dordaviprone and look forward to describing the future development path of ONC206 by the end of the year,” concluded Mr. Andriole.

Dordaviprone (ONC201)

Dordaviprone is an oral, first-in-class small molecule imipridone that selectively binds to the G-protein coupled dopamine receptor D2 (DRD2) and the mitochondrial protease ClpP.

Dordaviprone is being evaluated in the Phase 3 ACTION trial that is currently enrolling H3 K27M-mutant glioma patients at over 135 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 dordaviprone at one of two dosing frequencies or placebo. Participants are randomized to receive 625mg of dordaviprone once per week (the Phase 2 dosing regimen), 625mg on two consecutive days per week or placebo. The dose is scaled by body weight for patients <52.5kg.

Chimerix expects interim overall survival (OS) data in 2025 and final OS data in 2026. For more information, please visit clinicaltrials.gov

Chimerix recently engaged in the process to evaluate eligibility 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. Chimerix recently completed the Pre-Submission Meeting with the TGA and the TGA agreed that dordaviprone meets the criteria to advance to the second of three steps in the process, a Provisional Determination application. The meeting included an assessment that preliminary data is likely to provide a “major therapeutic advance” in H3 K27M-mutant glioma and that the ACTION study could provide pivotal confirmatory safety and efficacy data before the conclusion of the Provisional Registration period. Chimerix expects to work collaboratively with TGA as dordaviprone advances to the next step in the process over the coming months. Once submitted, the Provisional Determination review process is targeted for 20 working days. Should an application for Provisional Registration be submitted the review process is 255 working days. We expect a filing could occur around year end with possible commercial availability in 2026.

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. The dose escalation trials are currently dosing at a twice per day, three days per week schedule, which are expected to increase the duration of therapeutic exposure. To date, ONC206 has been generally well tolerated with no dose limiting toxicities as is currently being dosed in the expected therapeutic range. Chimerix expects to report preliminary safety and pharmacokinetic (PK) data from these

studies beginning in mid-2024.

Corporate

In March 2024, Chimerix announced the appointment of Marc D. Kozin as the newest member of the Company's Board of Directors. Mr. Kozin brings more than 35 years of experience in corporate and business strategy consulting and merger and acquisition advisory services. In addition, Patrick Machado has announced his retirement from the Chimerix Board effective at the Company's 2024 Annual Meeting of Stockholders in June, after ten years of service.

First Quarter 2024 Financial Results

Chimerix reported a net loss of $21.9 million, or $0.25 per basic and diluted share, for the first quarter of 2024. During the same period in 2023, Chimerix recorded a net loss of $21.4 million, or $0.24 per basic and diluted share.

Research and development expenses were $18.8 million for the first quarter of 2024 and the same period in 2023.

General and administrative expenses decreased to $5.5 million for the first quarter of 2024, compared to $5.7 million for the same period in 2023.

Chimerix's balance sheet at March 31, 2024 included $188.2 million of capital available to fund operations, approximately 89.6 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 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 1246220. 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, applications for Provisional Determination and Provisional Determination in Australia, plans for accelerated approval from other global regulators, completion of the ACTION study, 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 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, 2024	December 31, 2023
ASSETS		
Current assets:		
Cash and cash equivalents	$ 19,026	$ 27,661
Short-term investments, available-for-sale	140,002	155,174
Accounts receivable	1	4
Prepaid expenses and other current assets	4,003	6,271
Total current assets	163,032	189,110
Long-term investments	29,133	21,657
Property and equipment, net of accumulated depreciation	263	224
Operating lease right-of-use assets	1,354	1,482
Other long-term assets	260	301
Total assets	$ 194,042	$ 212,774
LIABILITIES AND STOCKHOLDERS' EQUITY		

Current liabilities:		
Accounts payable	$ 3,823	$ 2,851
Accrued liabilities	15,112	15,592
Total current liabilities	18,935	18,443
Line of credit commitment fee	-	125
Lease-related obligations	1,005	1,177
Total liabilities	19,940	19,745
Stockholders' equity:		
Preferred stock, $0.001 par value, 10,000,000 shares authorized at March 31, 2024 and December 31, 2023; no shares issued and outstanding as of March 31, 2024 and December 31, 2023; no shares issued and outstanding as of March 31, 2024 and	-	-
Common stock, $0.001 par value, 200,000,000 shares authorized at March 31, 2024 and December 31, 2023; 89,629,902 and 88,929,300 shares issued and outstanding as of March 31, 2024 and December 31, 2023, respectively	90	89
Additional paid-in capital	991,583	988,457
Accumulated other comprehensive (gain) loss, net	(178)	7
Accumulated deficit	(817,393)	(795,524)
Total stockholders' equity	174,102	193,029
Total liabilities and stockholders' equity	$ 194,042	$ 212,774

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

	Three Months Ended March 31,	
	2024	**2023**
Revenues:		
Contract and grant revenue	$ -	$ 234
Licensing revenue	-	49
Total revenues	-	283
Operating expenses:		
Research and development	18,844	18,822
General and administrative	5,546	5,679
Total operating expenses	24,390	24,501
Loss from operations	(24,390)	(24,218)
Other income:		
Interest income and other, net	2,521	2,846
Net loss	(21,869)	(21,372)
Other comprehensive (loss) income:		
Unrealized (loss) gain on debt investments, net	(185)	106
Comprehensive loss	$ (22,054)	$ (21,266)
Per share information:		
Net loss, basic and diluted	$ (0.25)	$ (0.24)
Weighted-average shares outstanding, basic and diluted	89,259,106	88,294,624

Source: Chimerix, Inc.