Chimerix Reports First Quarter 2022 Financial Results and Provides Operational Update

May 16, 2022

– Receiving up to $337.5 Million plus Royalties for Sale of Worldwide Rights of TEMBEXA to Emergent BioSolutions –

– Initiation of Phase 3 Randomized Study of ONC201 in H3 K27M Mutant Glioma Expected in 2022 –

– DSTAT Development Program Terminated; Resources Focused on Imipridone Platform –

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

DURHAM, N.C., May 16, 2022 (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, 2022 and provided an operational update.

"As announced earlier today, the sale of TEMBEXA® to Emergent BioSolutions, Inc. (Emergent) significantly strengthens our balance sheet at a time when access to capital within the industry is at a historic premium. With Emergent's expertise in global biodefense and our participation in future economics, this program is positioned to maximize value. We will now focus on developing a potentially life altering drug for glioma patients that harbor the H3 K27M mutation who have no other alternatives," said Mike Sherman, Chief Executive Officer of Chimerix. "Securing $225 million in an upfront payment with the possibility of additional milestones and royalties solidifies our ability to fund development of ONC201 and the imipridone platform without the uncertainty that arises from contracting with government entities."

"We continue our engagement with the U.S. Food and Drug Administration (FDA) regarding the development of ONC201. While we have not yet requested formal feedback on a potential NDA submission for accelerated approval, communication from the FDA makes it clear that the potential for accelerated approval is more challenging than previously anticipated. This is consistent with the evolving policy the agency has expressed towards single arm studies, generally. As such, we are prioritizing the initiation of a randomized Phase 3 study by year-end. Given the strength of the data already presented and the extent of the unmet patient need, we still believe an accelerated approval is possible and plan to complete the work already underway to support a potential NDA submission," added Mr. Sherman.

"Following an internal review of our pipeline, we will no longer be investing in the DSTAT program. This narrower focus of development resources will ensure we optimize our execution in bringing ONC201 to patients as quickly as possible," concluded Mr. Sherman.

Recent Highlights

Emergent Acquires Worldwide Rights to TEMBEXA

Today, Chimerix announced entering into an agreement with Emergent for the sale of TEMBEXA worldwide rights for $225 million upfront and additional milestones of up to $100 million to be paid contingent upon the execution of additional procurement awards from Biomedical Advanced Research and Development Authority (BARDA) following the base period. The closing payment and the milestone payments may be adjusted based on actual procurement value. Chimerix is also eligible to receive up to $12.5 million in regulatory milestones associated with the SymBio Pharmaceuticals Ltd. brincidofovir partnership to be assumed by Emergent. Chimerix may also earn a 20% royalty on future gross profit of TEMBEXA in the United States associated with volumes above 1.7 million treatment courses of therapy during the exclusivity period of TEMBEXA. Outside of the United States, the agreement also allows Chimerix to earn a 15% royalty on all gross profit associated with TEMBEXA sales during the exclusivity period of TEMBEXA on a market-to-market basis.

Subject to the satisfaction or waiver of the closing conditions, the companies expect the transaction may close as early as the second quarter of 2022. Chimerix is currently in negotiation with BARDA on the terms of a TEMBEXA procurement contract. Chimerix will continue to lead this negotiation until its conclusion. Entry into a TEMBEXA procurement contract with BARDA is a closing condition to the acquisition agreement with Emergent.

The FDA granted TEMBEXA tablets and oral suspension approval for the treatment of smallpox. TEMBEXA is approved for adult and pediatric patients and is the first and only smallpox therapy approved for neonates.

ONC201 for Recurrent H3 K27M-mutant Glioma

ONC201 is an orally administered small molecule dopamine receptor D2 (DRD2) antagonist and caseinolytic protease (ClpP) agonist for the treatment of recurrent gliomas that harbor the H3 K27M mutation.

The FDA had previously requested that Chimerix conduct a retrospective Natural Disease History (NDH) study of recurrent H3 K27M-mutant glioma. More recently, Chimerix was informed that the FDA no longer expects to rely on the outcome of a NDH study to inform a regulatory decision given the limitations inherent in NDH studies. Therefore, the Company plans to limit further investment in this study and will disclose the findings at a later date.

The Company plans to initiate a Phase 3 study of ONC201 in patients who harbor the H3 K27M-mutation. This study is designed to serve as the basis for either a confirmatory approval or first approval. Final study design and protocols are under review. Once agreement has been reached with the FDA, the Company will announce the final clinical design and timeline. While acknowledging the new regulatory sentiment with respect to single-arm data to support accelerated approval, the Company continues work to complete the safety database, clinical pharmacology studies and other items to

support a possible regulatory filing for accelerated approval.

In November, Chimerix reported data from the 50-patient cohort of ONC201 for the treatment of recurrent H3 K27M-mutant glioma at the Society for Neuro-Oncology (SNO) Annual Meeting. According to a BICR of the registration cohort, the overall response rate (ORR) was 20.0% (95% confidence interval (CI):10.0-33.7%) as determined by Response Assessment in Neuro-Oncology Criteria for High Grade Gliomas (RANO-HGG). The median duration of response was 11.2 months (95% CI: 3.8 – not reached) in addition to the median time to response of 8.3 months. The proportion of patients achieving either a RANO-HGG and/or RANO-LGG response was 30% (95% CI: 17.9 – 44.6%). One serious adverse event considered possibly ONC201-related by investigator was reported; however, the event was considered unlikely ONC201-related by sponsor assessment.

The FDA granted ONC201 Fast Track Designation for the treatment of adult recurrent H3 K27M-mutant HGG, Rare Pediatric Disease Designation for treatment of H3 K27M-mutant glioma, and Orphan Drug Designations for the treatment of glioblastoma and malignant glioma.

CMX521

In March, Chimerix presented a Late Breaking Oral presentation of CMX521 at the International Conference of Antiviral Research (ICAR). Promising preclinical efficacy data from the CMX521 program as a potential prophylactic and treatment of SARS-CoV-2 (COVID-19) infection was generated through a collaboration between Chimerix and the Rapidly Emerging Antiviral Drug Development Initiative (READDI) at the University of North Carolina at Chapel Hill (UNC). READDI is a global public-private partnership founded at UNC by the UNC Eshelman School of Pharmacy, UNC School of Medicine, Gilling School of Global Public Health, Eshelman Institute for Innovation and the Structural Genomics Consortium. Development remains ongoing with this collaboration.

First Quarter 2022 Financial Results

Chimerix reported a net loss of $24.8 million, or $0.28 per basic and diluted share, for the first quarter of 2022. During the same period in 2021, Chimerix recorded a net loss of $97.4 million, or $1.21 per basic and diluted share.

Revenues for the first quarter of 2022 decreased to $15,000, compared to $1.4 million for the same period in 2021. This difference was driven by a lack of BARDA reimbursement revenue in 2022 versus 2021 for TEMBEXA development.

Research and development expenses increased to $19.0 million for the first quarter of 2022, compared to $11.9 million for the same period in 2021 driven primarily by higher investments in ONC201 and ONC206 compared to the same period last year.

General and administrative expenses increased to $5.6 million for the first quarter of 2022, compared to $4.1 million for the same period in 2021.

Chimerix recorded acquired in-process research and development expenses of $82.9 million for the first quarter of 2021 related to the acquisition of Oncoceutics, Inc.

Loss from operations was $24.8 million for the first quarter of 2022, compared to a loss from operations of $97.5 million for the same period in 2021 driven by the first quarter 2021 in-process research and development charge of $82.9 million related to the acquisition of Oncoceutics, Inc.

Chimerix's balance sheet at March 31, 2022 included $53.4 million of capital available to fund operations, approximately 87.4 million outstanding shares of common stock and no outstanding debt as the $14 million note related to the purchase price of Oncoceutics from January 2021 was repaid in the first quarter of 2022.

Chimerix expects to execute the transaction with Emergent as early as the second quarter of 2022 with payment of $225 million payable at closing.

Conference Call and Webcast

Chimerix will host a conference call and live audio webcast to discuss first quarter 2022 financial results and provide a business update today at 8:30 a.m. ET. To access the live conference call, please dial 877-354-4056 (domestic) or 678-809-1043 (international) at least five minutes prior to the start time and refer to conference ID 3535104.

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 execution of a procurement contract for TEMBEXA and the amount and timing of TEMBEXA shipment into the SNS; the sale of our TEMBEXA program and related assets to Emergent, which is subject to certain closing conditions which may not be completed on a timely basis, if at all; risks associated with the receipt of future milestone payments and royalty payments under the Emergent transaction, if completed; the timing and nature of regulatory submissions for ONC201; and results from the BICR of the 50- patient cohort of ONC201 for the treatment of recurrent H3 K27M-mutant glioma. Among the factors and risks that could cause actual results to differ materially from those indicated in the forward-looking statements are risks that Chimerix will not obtain a procurement contract for TEMBEXA in smallpox in a timely manner, on favorable terms, or at all; risks that the initial delivery or any subsequent deliveries of TEMBEXA will not occur as planned, or at all; risks that the current pre-clinical or clinical study data for ONC201 or CMX521 will not support accelerated, or any, regulatory approval; the anticipated benefits of the acquisition of Oncoceutics or the sale of our TEMBEXA program to Emergent may not be realized; risks that Chimerix's current BCV manufacturing efforts may not satisfy the requirements of any procurement award; risks that Chimerix's reliance on a sole source third-party manufacturer for drug supply; risks that ongoing or future trials may not be successful or replicate previous trial results, or may not be predictive of real-world results or of results in subsequent trials; risks and uncertainties relating to competitive products and technological changes that may limit demand for our drugs; risks that our drugs may be precluded from commercialization by the proprietary rights of third parties; 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 2022	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 31,957	$ 15,397
Short-term investments, available-for-sale	21,421	72,970
Inventories	3,406	2,760
Prepaid expenses and other current assets	5,766	4,678
Total current assets	62,550	95,805
Long-term investments	-	2,022
Property and equipment, net of accumulated depreciation	229	253
Operating lease right-of-use assets	2,298	2,404
Other long-term assets	439	56
Total assets	$ 65,516	$ 100,540
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 3,494	$ 2,788
Accrued liabilities	11,718	13,108
Note payable	-	14,000
Total current liabilities	15,212	29,896
Loan Fees	250	-
Lease-related obligations	2,256	2,392
Total liabilities	17,718	32,288
Stockholders' equity:		
Preferred stock, $0.001 par value, 10,000,000 shares authorized at March 31, 2022 and December 31, 2021; no shares issued and outstanding as of March 31, 2022 and December 31, 2021; no shares issued and outstanding as of March 31, 2022 and	-	-
Common stock, $0.001 par value, 200,000,000 shares authorized at March 31, 2022 and December 31, 2021; 87,436,180 and 86,884,266 shares issued and outstanding as of March 31, 2022 and December 31, 2021, respectively	87	87
Additional paid-in capital	958,147	953,782
Accumulated other comprehensive loss, net	(73)	(21)
Accumulated deficit	(910,363)	(885,596)
Total stockholders' equity	47,798	68,252
Total liabilities and stockholders' equity	$ 65,516	$ 100,540

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

	Three Months Ended March 31,	
	2022	2021
Revenues:		
Contract and grant revenue	$ -	$ 1,433
Licensing revenue	15	2
Total revenues	15	1,435
Cost of goods sold	114	-
Gross Profit	(99)	1,435
Operating expenses:		
Research and development	19,040	11,862
General and administrative	5,632	4,136
Acquired in-process research and development	-	82,890
Total operating expenses	24,672	98,888
Loss from operations	(24,771)	(97,453)
Other income:		
Interest income and other, net	4	38
Net loss	(24,767)	(97,415)
Other comprehensive loss:		
Unrealized loss on debt investments, net	(52)	(43)
Comprehensive loss	$ (24,819)	$ (97,458)
Per share information:		
Net loss, basic and diluted	$ (0.28)	$ (1.21)
Weighted-average shares outstanding, basic and diluted	87,088,804	80,204,094

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Source: Chimerix, Inc.