Chimerix Reports Fourth Quarter and Year End 2021 Financial Results and Provides Operational Update

March 1, 2022

– TEMBEXA RFP Response Submitted and Under Review with BARDA –

– Pre-Clinical CMX521 Data Accepted for Late Breaking Oral Presentation at International Conference on Antiviral Research –

– ONC201 Program Remains on Track –

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

DURHAM, N.C., March 01, 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 fourth quarter and full-year ended December 31, 2021 and provided an operational update.

"We achieved important milestones in 2021 with our first U.S. Food and Drug Administration (FDA) approval for TEMBEXA® as a medical countermeasure for smallpox and reported compelling late-stage clinical data from our ONC201 program to treat recurrent H3 K27M-mutant glioma," said Mike Sherman, Chief Executive Officer of Chimerix. "We are well positioned to build on that momentum in 2022. We submitted our response to Biomedical Advanced Research and Development Authority's (BARDA) request for proposal (RFP) ahead of the February 7 deadline, and our RFP submission is now under review with respect to a potential TEMBEXA procurement contract. We expect revenue from this contract will provide ongoing support for the continued development of our robust clinical pipeline.

"Last week, we announced exciting preclinical data from our CMX521 program showing potential as a prophylaxis and treatment for COVID-19. CMX521 is positioned for rapid clinical development to help address the continuing need for novel COVID-19 therapies with improved safety, activity and/or resistance profiles.

"Finally, we plan to discuss with FDA the design of a randomized trial for ON201 in frontline H3 K27M positive glioma patients, which we expect to conduct in tandem with a potential New Drug Application (NDA) review. We continue to gather data for the natural disease history evaluation of H3 K27M positive glioma patients, which along with our previously reported efficacy data, and additional safety, pharmacology, and chemistry, manufacturing and controls (CMC) studies, will form the basis for our filing," continued Mr. Sherman.

Recent Highlights

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.

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 blinded independent central review (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. Full safety data collection and analysis for this cohort is ongoing.

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.

Chimerix plans to meet with the FDA in the first half of 2022 to discuss a first-line randomized, placebo-controlled Phase 3 trial of ONC201 in combination with radiation therapy. The Company plans to initiate this study of patients who harbor the H3 K27M-mutation during the second half of 2022. In addition, the Company is conducting a retrospective natural history study, completing other supporting clinical pharmacology studies, collecting CMC supporting data and compiling the safety package which it plans to review with the FDA in anticipation of a potential submission.

TEMBEXA for Smallpox

In June, 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. The oral suspension formulation is particularly important for patients who have difficulty swallowing due to age or medical status.

TEMBEXA potentially fills an important role as a treatment countermeasure to smallpox; it has a differentiated mechanism of action, a relatively high barrier to resistance, low pill burden, is approved for a broad population, and is available in both tablet and suspension formulations. In September, an article was published in the peer reviewed journal, *Antiviral Research*, providing a thorough assessment of TEMBEXA as a medical countermeasure for smallpox. The article can be accessed here.

In December, BARDA issued a sole source RFP to procure up to 1.7 million treatment courses of therapy of TEMBEXA. The Company submitted a response to the RFP and the submission is currently under review by BARDA. Chimerix is poised to deliver initial quantities of TEMBEXA to the strategic national stockpile upon completion of negotiations.

Dociparstat Sodium (DSTAT) for AML

Chimerix continues enrollment in the Phase 3 **D**ociparstat in **A**ML with **S**tandard C**h**emotherapy (DASH AML) study of DSTAT. The multicenter, randomized, double-blind, placebo-controlled, parallel-group study is being conducted to evaluate the efficacy and safety of DSTAT in combination with standard intensive induction and consolidation chemotherapy for the treatment of newly diagnosed AML patients. Enrollment of this study has proceeded more slowly than expected due to ongoing hospital staffing shortages related to COVID-19 and the competitive nature of enrolling subjects in this patient population. As such, the Company does not expect to complete enrollment of the first 80 evaluable patients by year end. Chimerix is evaluating a number of options to accelerate the development of DSTAT.

CMX521 for SARS-CoV-2 (COVID-19)

In February, Chimerix announced the acceptance of a Late Breaking Oral Presentation of CMX521 at the International Conference on Antiviral Research (ICAR). The presentation is scheduled to take place on Wednesday, March 23, 2022 from 12:15–1:00 PM PT in Seattle, WA.

Promising pre-clinical efficacy data showing CMX521 as a potential prophylactic and treatment of SARS-CoV-2 (COVID-19) infection was generated through collaboration between Chimerix and the Rapidly Emerging Antiviral Drug Development Initiative (READDI) at the University of North Carolina (UNC). READDI is a global public-private partnership founded by the UNC Eshelman School of Pharmacy, UNC School of Medicine, Gillings School of Global Public Health, Eshelman Institute for Innovation and the Structural Genomics Consortium.

Monotherapy prophylactic administration of aerosol CMX521 every eight hours starting eight hours prior to infection reduced average viral titers in lung on day four post-infection by 3.62 $\log_{10}$ (>99.9% reduction) and prevented weight loss/clinical progression versus placebo. The model used in this study was also used in the development of another antiviral therapy which has Emergency Use Authorization for SARS-CoV-2 in the United States. Antiviral efficacy was also demonstrated with monotherapy treatment when CMX521 was initiated post-infection. When administered within 16 hours post-infection, CMX521 significantly reduced SARS-CoV-2 in the lung (Kruskal-Wallis $p<0.0001$) and protected mice from clinical symptoms of disease including weight loss and adverse lung pathology ($p<0.0001$) at day four post-infection relative to placebo.

Fourth Quarter 2021 Financial Results

Chimerix's balance sheet at December 31, 2021 included $90.4 million of capital available to fund operations, a $14 million note payable, and approximately 86.9 million outstanding shares of common stock. In January 2022, the Company entered into a four-year $50.0 million revolving credit facility with Silicon Valley Bank. The Company has not drawn on this facility to date and has no obligation to use the credit facility. The Company views the credit facility as a resource that may supplement its financial position by providing an alternative source of capital that can be utilized on an as-needed basis, for example, in advance of an anticipated (or future) shipment of TEMBEXA treatment courses to BARDA over the term of the credit facility.

Chimerix reported a net loss of $39.5 million, or $0.45 per basic and diluted share, for the fourth quarter of 2021, which included a $20 million success milestone payment to the legacy Oncoceutics shareholders in relation to the achievement of a 20% overall response rate by RANO-HGG for ONC201. During the same period in 2020, Chimerix recorded a net loss of $11.7 million, or $0.19 per basic and diluted share.

With the completion of the Company’s legacy 2011 research and development contract with BARDA in the third quarter of 2021, revenue for the fourth quarter of 2021 decreased to $46,000, compared to $1.1 million for the same period in 2020.

Research and development expenses increased to $34.3 million for the three-month period ended December 31, 2021, compared to $8.7 million for the same period in 2020. The increase is primarily related to the payment of the ONC201 $20.0 million success milestone.

General and administrative expenses increased to $5.2 million for the fourth quarter of 2021, compared to $4.2 million for the same period in 2020.

Full Year 2021 Financial Results

Chimerix reported a net loss of $173.2 million, or $2.04 per basic and diluted share, for the year ended December 31, 2021. For the year ended December 31, 2020, Chimerix recorded a net loss of $43.5 million, or $0.70 per basic and diluted share. The increase was primarily driven by the charge for the acquisition of in-process research and development and subsequent development expense related to the acquisition of Oncoceutics, Inc and its lead compound, ONC201, in January 2021.

Revenues for 2021 decreased to $2.0 million, compared to $5.4 million in 2020.

Research and development expenses increased to $73.8 million for the year ended December 31, 2021, compared to $36.2 million for the year ended December 31, 2020. Of which, $20.0 million relates to the success milestone paid to the legacy shareholders of Oncoceutics for the achievement of a 20% overall response rate by RANO-HGG for ONC201.

General and administrative expenses increased to $18.7 million for the year ended December 31, 2021, compared to $13.7 million for the year ended December 31, 2020.

Chimerix recorded acquired in-process research and development expenses of $82.9 million for the year ended December 31, 2021 related to the acquisition of Oncoceutics.

Conference Call and Webcast

Chimerix will host a conference call and live audio webcast to discuss fourth quarter and full-year 2021 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 9874598.

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. In June 2021, the U.S. Food and Drug Administration granted approval of TEMBEXA for the treatment of smallpox as a medical countermeasure. The Company has two other advanced clinical-stage development programs, ONC201 and dociparstat sodium (DSTAT). ONC201 is in development for recurrent H3 K27M-mutant glioma. DSTAT is in development as a potential first-line therapy in acute myeloid leukemia.

About TEMBEXA

TEMBEXA is an oral antiviral formulated as 100 mg tablets and 10 mg/mL oral suspension dosed once weekly for two weeks. TEMBEXA is indicated for the treatment of human smallpox disease caused by variola virus in adult and pediatric patients, including neonates. TEMBEXA is not indicated for the treatment of diseases other than human smallpox disease. The effectiveness of TEMBEXA for the treatment of smallpox disease has not been determined in humans because adequate and well-controlled field trials have not been feasible and inducing smallpox disease in humans to study the drug's efficacy is not ethical. TEMBEXA efficacy may be reduced in immunocompromised patients based on studies in immune deficient animals.

TEMBEXA (brincidofovir) is a nucleotide analog lipid-conjugate designed to mimic a natural monoacyl phospholipid to achieve effective intracellular concentrations of the active antiviral metabolite, cidofovir diphosphate. Cidofovir diphosphate exerts its orthopoxvirus antiviral effects by acting as an alternate substrate inhibitor for viral DNA synthesis mediated by viral DNA polymerase.

IMPORTANT SAFETY INFORMATION Including BOXED WARNING

WARNING: INCREASED RISK FOR MORTALITY WHEN USED FOR LONGER DURATION

An increased incidence of mortality was seen in TEMBEXA-treated subjects compared to placebo-treated subjects in a 24-week clinical trial when TEMBEXA was evaluated in another disease.

WARNINGS AND PRECAUTIONS

Elevations in Hepatic Transaminases and Bilirubin: May cause increases in serum transaminases (ALT or AST) and serum bilirubin. Monitor liver laboratory parameters before and during treatment.

Diarrhea and Other Gastrointestinal Adverse Events: Diarrhea and additional gastrointestinal adverse events including nausea, vomiting, and abdominal pain may occur. Monitor patients, provide supportive care, and if necessary, do not give the second and final dose of TEMBEXA.

Coadministration with Related Products: TEMBEXA should not be co-administered with intravenous cidofovir.

Carcinogenicity: TEMBEXA is considered a potential human carcinogen. Do not crush or divide TEMBEXA tablets and avoid direct contact with broken or crushed tablets or oral suspension.

Male Infertility: Based on testicular toxicity in animal studies, TEMBEXA may irreversibly impair fertility in individuals of reproductive potential.

ADVERSE REACTIONS

Common adverse reactions (adverse events assessed as causally related by the investigator in ≥ 2% of subjects) experienced in the first 2 weeks of dosing with TEMBEXA were diarrhea, nausea, vomiting and abdominal pain.

USE IN SPECIFIC POPULATIONS

Pregnancy

Based on findings from animal reproduction studies, TEMBEXA may cause fetal harm when administered to pregnant individuals. Pregnancy testing should be performed before initiation of TEMBEXA in individuals of childbearing potential to inform risk. An alternative therapy should be used to treat smallpox during pregnancy, if feasible.

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, results from the BICR of the 50- patient cohort of ONC201 for the treatment of recurrent H3 K27M-mutant glioma, the status of Chimerix's oncology programs, and the manufacturing, potential benefits and government procurement of TEMBEXA. Among the factors and risks that could cause actual results to differ materially from those indicated in the forward-looking statements are 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 may not be realized; the ability to generate positive results in a Phase 3 study in acute myeloid leukemia and subsequent approval for DSTAT; risks that Chimerix will not obtain a procurement contract for TEMBEXA in smallpox in a timely manner or at all; Chimerix's current BCV manufacturing efforts may not satisfy the requirements of any procurement award; 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)

	December 31, 2021	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 15,397	$ 46,989
Short-term investments, available-for-sale	72,970	31,973
Accounts receivable	-	340
Inventories	2,760	-
Prepaid expenses and other current assets	4,678	2,356
Total current assets	95,805	81,658
Long-term investments	2,022	-
Property and equipment, net of accumulated depreciation	253	214
Operating lease right-of-use assets	2,404	2,825
Other long-term assets	56	26
Total assets	$ 100,540	$ 84,723
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,788	$ 1,283
Accrued liabilities	13,108	7,250
Note payable	14,000	-
Total current liabilities	29,896	8,533
Lease-related obligations	2,392	2,814
Total liabilities	32,288	11,347
Stockholders' equity:		
Preferred stock, $0.001 par value, 10,000,000 shares authorized at December 31, 2021 and 2020; no shares issued and outstanding as of December 31, 2021 and 2020	-	-
Common stock, $0.001 par value, 200,000,000 shares authorized at December 31, 2021 and 2020; 86,884,266 and 62,816,039 shares issued and outstanding as of December 31, 2021 and 2020, respectively	87	63
Additional paid-in capital	953,782	785,673
Accumulated other comprehensive loss, net	(21)	-
Accumulated deficit	(885,596)	(712,360)
Total stockholders' equity	68,252	73,376
Total liabilities and stockholders' equity	$ 100,540	$ 84,723

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

	Three Months Ended December 31,		Years Ended December 31,	
	2021	2020	2021	2020
Revenues:				
Contract revenue	$ -	$ 1,116	$ 1,928	$ 5,274
Licensing revenue	46	4	51	98

Total revenues	46	1,120	1,979	5,372
Operating expenses:				
Research and development	34,337	8,687	73,817	36,232
General and administrative	5,241	4,190	18,672	13,656
Acquired in-process research and development	-	-	82,890	-
Total operating expenses	39,578	12,877	175,379	49,888
Loss from operations	(39,532)	(11,757)	(173,400)	(44,516)
Other income:				
Interest income and other, net	34	82	164	994
Net loss	(39,498)	(11,675)	(173,236)	(43,522)
Other comprehensive loss:				
Unrealized loss on investments, net	(21)	(33)	(21)	(35)
Comprehensive loss	$ (39,519)	$ (11,708)	$ (173,257)	$ (43,557)
Per share information:				
Net loss, basic and diluted	$ (0.45)	$ (0.19)	$ (2.04)	$ (0.70)
Weighted-average shares outstanding, basic and diluted	86,867,070	62,702,181	84,930,255	62,183,947

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Source: Chimerix, Inc.