Chimerix Reports First Quarter 2021 Financial Results and Provides Operational Update

May 6, 2021

– BCV PDUFA Date Set for July 7 and ONC201 Blinded Independent Central Review Expected in Second Half of 2021 –

– DSTAT COVID 19 Trial Advances to Cohort 3 at Higher Dose –

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

DURHAM, N.C., May 06, 2021 (GLOBE NEWSWIRE) -- Chimerix (NASDAQ:CMRX), a biopharmaceutical company focused on accelerating the development of medicines to treat cancer and other serious diseases, today reported financial results for the first quarter ended March 31, 2021 and provided an operational update.

"As we continue execution toward important milestones in the second half of this year, we are also positioning the company for the next phase of growth. This is highlighted by the recent appointment of Vicki Vakiener who brings extensive commercial and oncology experience to our Board of Directors," said Mike Sherman, Chief Executive Officer of Chimerix.

"We look forward to our July 7th Prescription Drug User Fee Act (PDUFA) date for BCV as a medical countermeasure for smallpox. We responded to the Small Business Sources Sought Notice (SSN) issued in late March by Biomedical Advanced Research and Development Authority (BARDA), which is another formal step toward a potential procurement contract. We also remain on track to have the blinded independent central review for ONC201 in the second half of 2021. This response data, and other important measures of clinical benefit and safety, may form the basis for an NDA submission seeking accelerated approval of ONC201 for patients with H3 K27M-mutant glioma. In addition, we continue important development of DSTAT in both the Phase 3 DASH AML and Phase 2 COVID-19 trials," continued Mr. Sherman.

Recent Highlights

BCV for Smallpox

In late March 2021, BARDA issued an SSN seeking information on availabilities and capabilities for procuring, stockpiling, and investing in the development of FDA-approved smallpox antiviral(s) with alternative mechanism(s) of action to TPOXX®. Chimerix responded to the SSN with information on our relevant capabilities, experience and interest. Chimerix remains on pace to deliver initial quantities of BCV under a potential stockpile agreement as early as a few months after FDA approval, if received.

DSTAT for Acute Lung Injury Patients with COVID-19

Chimerix today reported partial data from the second cohort of the ongoing Phase 2 study of DSTAT for COVID-19 patients, as the biomarker analysis is not yet available. In the second cohort, based on a switch to 2:1 randomization, eight patients were randomized to receive a 4mg/kg bolus dose of DSTAT followed by a continuous infusion of 0.325mg/kg/hour (as opposed to 0.25mg/kg/hr in cohort one), and four patients were randomized to receive placebo. The trial enrolled patients with either NIAID 3 (more severe at baseline) or NIAID 4 (less severe at baseline) disease. None of the patients treated with placebo entered the trial with the more severe disease while two DSTAT patients were identified with more severe disease at baseline. One patient randomized to DSTAT required transfer to the ICU within 24 hours of admission, along with discontinuation of DSTAT due to prohibited concomitant medications and died after the day 28 endpoint. One patient randomized to placebo withdrew consent before treatment. All remaining seven patients receiving DSTAT and three patients receiving placebo recovered by day 28. As with the first cohort, the ability to gain insight into efficacy signals in this cohort is limited due to the small sample size and random demographic imbalances. Supportive biomarker analysis will be performed as those results are available. The Data Safety Monitoring Board recommended advancing to cohort three, which will include approximately 50 patients, at the higher cohort two dose.

DSTAT for AML

Chimerix recently began enrolling patients in the Phase 3 **D**ociparstat in **A**ML with **S**tandard C**h**emotherapy (DASH AML) study of DSTAT for the treatment of AML. The multicenter, randomized, double-blind, placebo-controlled, parallel-group study will evaluate the efficacy and safety of DSTAT in combination with standard intensive induction and consolidation chemotherapy for the treatment of newly-diagnosed AML patients. Chimerix expects to unblind data following enrollment of the first 80 evaluable patients in this study to assess complete response rates and minimal residual disease rates between the study arm and the control arm. This analysis is expected to take place in 2022.

Imipridones and ONC201

In January, Chimerix announced the acquisition of Oncoceutics, Inc., a privately-held, clinical-stage biotechnology company developing imipridones, a novel class of small molecule anti-cancer compounds. Oncoceutics' lead product candidate, ONC201, has been shown in clinical testing to selectively induce cell death in multiple cancer types. Final analysis of results from the registration cohort of 50 patients in clinical trials for recurrent H3 K27M-mutant glioma and a blinded independent central review is expected in the second half of this year.

In addition, Phase 1 clinical trials for ONC206, the second product candidate in Oncoceutics' pipeline, were recently initiated and IND-enabling work for a third imipridone candidate, ONC212, is ongoing.

Corporate

In January, Chimerix closed an underwritten public offering of 13.5 million shares of common stock. The net proceeds to Chimerix from the offering, after deducting underwriting discounts and commissions and other offering expenses, were $107.8 million.

In April 2021, Vicki Vakiener was appointed to the Company's board of directors. Ms. Vakiener currently serves as Chief Commercial Officer of Epizyme, Inc., where she leads the company's commercial efforts and has overseen the successful launch of tazemetostat in two indications. During her more than 20 years of experience in oncology, Ms. Vakiener has held positions of leadership across Johnson & Johnson's pharmaceuticals and diagnostics businesses.

Expected 2021 Milestones

- FDA PDUFA action date set for July 7, 2021 for BCV smallpox NDA.
- Potential procurement agreement for BCV around the time of FDA decision on smallpox NDA, if favorable.
- Completion of Phase 2 trial of DSTAT in COVID-19 related ALI.
- Completion of BCV drug product manufacturing to support potential shipments to the SNS of up to $100 million.
- Blinded independent central review of 50-subject registration cohort of ONC201 in recurrent H3 K27M-mutant glioma.

First Quarter 2021 Financial Results

Chimerix reported a net loss of $ 97.4 million, or $1.21 per basic and diluted share, for the first quarter of 2021. During the same period in 2020, Chimerix recorded a net loss of $10.4 million, or $0.17 per basic and diluted share.

Revenues for the first quarter of 2021 increased to $1.4 million, compared to $1.2 million for the same period in 2020.

Research and development expenses increased to $11.9 million for the first quarter of 2021, compared to $8.9 million for the same period in 2020.

General and administrative expenses increased to $4.1 million for the first quarter of 2021, compared to $3.2 million for the same period in 2020.

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 $97.5 million for the first quarter of 2021, compared to a loss from operations of $10.9 million for the same period in 2020.

Chimerix's balance sheet at March 31, 2021 included $152.5 million of capital available to fund operations, $14.0 million in a note payable related to the Oncoceutics transaction, and approximately 86.2 million outstanding shares of common stock.

Conference Call and Webcast

Chimerix will host a conference call and live audio webcast to discuss first quarter 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 5156727.

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 development-stage biopharmaceutical company dedicated to accelerating the advancement of innovative medicines that make a meaningful impact in the lives of patients living with cancer and other serious diseases. Our three most advanced clinical-stage development programs are BCV, ONC201 and DSTAT. BCV is an antiviral drug candidate developed as a potential medical countermeasure for smallpox and is currently under review for regulatory approval in the United States. ONC201 is currently in a registrational clinical program for recurrent H3 K27M-mutant glioma and a blinded independent central review is expected later this year. DSTAT is in development as a potential first-line therapy in acute myeloid leukemia and as a potential treatment for acute lung injury in hospitalized COVID-19 patients.

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 timing of the confirmatory response rate assessment for ONC201; the sufficiency of the data from the current Phase 2 clinical trial of ONC201 to support accelerated regulatory approval; the anticipated benefits of Chimerix's acquisition of Oncoceutics; the completion of a Phase 3 study in acute myeloid leukemia with DSTAT; Chimerix's ability to obtain regulatory approval for its clinical candidates, including DSTAT, ONC201 and BCV; and Chimerix's ability to enter into a procurement agreement for the sale of BCV to the SNS. 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 Phase 2 clinical trial data for ONC201 will not support accelerated, or any, regulatory approval; the anticipated benefits of the acquisition of Oncoceutics may not be realized; BCV may not obtain regulatory approval from the FDA or such approval may be delayed or conditioned; risks that Chimerix will not obtain a procurement contract for BCV in smallpox in a timely manner or at all; 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 2021	December 31, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	$ 32,080	$ 46,989
Short-term investments, available-for-sale	112,898	31,973
Accounts receivable	482	340
Prepaid expenses and other current assets	2,677	2,356
Total current assets	148,137	81,658
Long-term investments	7,548	-
Property and equipment, net of accumulated depreciation	218	214
Operating lease right-of-use assets	2,717	2,825
Other long-term assets	29	26
Total assets	$ 158,649	$ 84,723
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,181	$ 1,283
Accrued liabilities	6,067	7,250
Note payable	14,000	-
Total current liabilities	22,248	8,533
Lease-related obligations	2,752	2,814
Total liabilities	25,000	11,347
Stockholders' equity:		
Preferred stock, $0.001 par value, 10,000,000 shares authorized at March 31, 2021 and December 31, 2020; no shares issued and outstanding as of March 31, 2021 and December 31, 2020	-	-
Common stock, $0.001 par value, 200,000,000 shares authorized at March 31, 2021 and December 31, 2020; 86,208,279 and 62,816,039 shares issued and outstanding as of March 31, 2021 and December 31, 2020, respectively	86	63
Additional paid-in capital	943,381	785,673
Accumulated other comprehensive loss, net	(43)	-
Accumulated deficit	(809,775)	(712,360)
Total stockholders' equity	133,649	73,376
Total liabilities and stockholders' equity	$ 158,649	$ 84,723

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

	Three Months Ended March 31,	
	2021	2020
Revenues:		

Contract and grant revenue	$ 1,433	$ 1,171
Licensing revenue	2	70
Total revenues	1,435	1,241
Operating expenses:		
Research and development	11,862	8,949
General and administrative	4,136	3,205
Acquired in-process research and development	82,890	-
Total operating expenses	98,888	12,154
Loss from operations	(97,453)	(10,913)
Other income:		
Interest income and other, net	38	493
Net loss	(97,415)	(10,420)
Other comprehensive loss:		
Unrealized loss on debt investments, net	(43)	(46)
Comprehensive loss	$ (97,458)	$ (10,466)
Per share information:		
Net loss, basic and diluted	$ (1.21)	$ (0.17)
Weighted-average shares outstanding, basic and diluted	80,204,094	61,742,035

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Source: Chimerix, Inc.