Chimerix Reports Third Quarter 2020 Financial Results and Provides Operational Update

November 5, 2020

– Completed Rolling NDA Submissions for Both BCV Tablet and Suspension Formulations as Medical Countermeasure for Smallpox –

– First Patient Visit for DSTAT Phase 3 AML Study Expected in Early 2021 –

– Company Well Capitalized Through Several Expected Upcoming Milestones –

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

DURHAM, N.C., Nov. 05, 2020 (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 third quarter ended September 30, 2020 and provided an operational update.

“Throughout the third quarter we continued to make significant progress across a number of key initiatives,” said Mike Sherman, Chief Executive Officer of Chimerix. “Of particular note was the completion of our rolling submissions to the U.S. Food and Drug Administration (FDA) for the approval of brincidofovir (BCV) as a medical countermeasure for smallpox. This milestone brings us one step closer to the company’s first regulatory approval and to securing a potential procurement contract with BARDA to supply the U.S. Strategic National Stockpile (SNS), which we expect to take place around the time of a potential FDA approval. In addition, we expect to be notified of our Prescription Drug User Fee Act (PDUFA) date relating to these submissions before the end of the year.”

“In addition, we expect to initiate our Phase 3 study of DSTAT for the treatment of acute myeloid leukemia (AML) in early 2021. We were particularly encouraged by a recent meta-analysis of 11,151 patients covering 81 separate studies published in the *Journal of the American Medical Association Oncology (Short, et al)* in which a link was suggested between minimal residual disease (MRD) status and outcomes in patients with AML. Specifically, this large cohort meta-analysis showed that MRD-negative AML patients experience superior disease-free survival and overall survival rates when compared to patients that are MRD-positive (average hazard ratios of 0.37 and 0.36, for overall survival and disease-free survival respectively). The study suggests that evaluation of MRD status in AML patients may allow for an earlier assessment of therapeutic effects and could lead to acceleration in the development of novel AML therapeutics. This meta-analysis underscores the importance of the MRD assessment that we will undertake following the first 80 evaluable patients in our Phase 3 study in order to better interpret the relapse-free survival and overall survival advantages observed with DSTAT in our smaller Phase 2 study.”

“Due to the complex and rapidly changing landscape of the current pandemic, we cannot predict when we will complete enrollment in our Phase 2 trial of DSTAT in acute lung injury (ALI) in COVID-19 but do anticipate sharing initial topline data in the first quarter of 2021,” concluded Mr. Sherman.

Recent Highlights

- Completed the rolling NDA submissions for BCV tablets and for BCV suspension as a medical countermeasure for smallpox
- Published manuscript in *Advances in Therapy,* titled "Design and Rationale of a Randomized, Double-Blind, Placebo-Controlled, Phase 2/3 Study Evaluating Dociparstat in Acute Lung Injury Associated with Severe COVID-19.”
- Presented data in support of the multi-stage modeling and simulation approach used to determine BCV dosing for the treatment of smallpox in humans at the World Health Organization Advisory Committee on Variola Virus Research

Expected Upcoming Milestones

- FDA notification during the fourth quarter of 2020 regarding the acceptance of the BCV NDA submissions and assignment of a PDUFA date
- Initiation of Phase 3 trial of DSTAT in first line AML in early 2021
- Potential procurement agreement for BCV around the time of FDA decision on smallpox NDA
- FDA decision on BCV smallpox NDA in 2021
- Completion of Phase 2 trial of DSTAT in COVID-19 related ALI in 2021
- Completion of BCV drug product manufacturing to support potential shipments to the SNS of up to $100 million in 2021

Third Quarter 2020 Financial Results

Chimerix reported a net loss of $11.4 million, or $0.18 per basic and diluted share, for the third quarter of 2020. During the same period in 2019, Chimerix recorded a net loss of $73.7 million, or $1.26 per basic and diluted share.

Revenues for the third quarter of 2020 decreased to $1.6 million, compared to $2.0 million for the same period in 2019.

Research and development expenses increased to $10.0 million for the third quarter of 2020, compared to $7.5 million for the same period in 2019.

The increase was driven by clinical trial expenses associated with the development of DSTAT.

General and administrative expenses decreased to $3.2 million for the third quarter of 2020, compared to $4.0 million for the same period in 2019.

Loss from operations was $11.6 million for the third quarter of 2020, compared to a loss from operations of $74.6 million for the same period in 2019, which included $65 million associated with the licensing of DSTAT in that period.

Chimerix's balance sheet at September 30, 2020 included $87.8 million of capital available to fund operations, no debt, and approximately 62.6 million outstanding shares of common stock.

Conference Call and Webcast

Chimerix will host a conference call and live audio webcast to discuss third quarter 2020 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 6085937.

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. Its two clinical-stage development programs are dociparstat sodium (DSTAT) and brincidofovir (BCV).

DSTAT is a potential first-in-class glycosaminoglycan compound derived from porcine heparin that, compared to commercially available forms of heparin, may be dosed at higher levels without associated bleeding-related complications. DSTAT is being studied in a Phase 2/3 trial to assess safety and efficacy in adults with acute lung injury with underlying COVID-19. A Phase 3 trial protocol to study DSTAT in acute myeloid leukemia has been developed in alignment with the US Food and Drug Administration (FDA) and first patient visit is expected in early 2021. 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. For further information, please visit the Chimerix website, www.chimerix.com.

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, Chimerix's ability to obtain regulatory approval for BCV; the timing and receipt of a potential procurement contract for BCV in smallpox; and the initiation, progress and results of the Phase 3 clinical trial of DSTAT in AML and the Phase 2/3 clinical trial of DSTAT in ALI associated with COVID-19. Among the factors and risks that could cause actual results to differ materially from those indicated in the forward-looking statements are risks that DSTAT may not obtain regulatory approval from the FDA or such approval may be delayed or conditioned; risks that development activities related to DSTAT may not be completed on time or at all; risks that DSTAT may not achieve the endpoints of its clinical trials; 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)

	September 30, 2020	December 31, 2019

ASSETS		
Current assets:		
Cash and cash equivalents	$ 38,130	$ 16,901
Short-term investments, available-for-sale	49,635	96,574
Accounts receivable	378	1,233
Prepaid expenses and other current assets	2,100	3,385
Total current assets	90,243	118,093
Property and equipment, net of accumulated depreciation	291	540
Operating lease right-of-use assets	2,943	709
Other long-term assets	27	34
Total assets	$ 93,504	$ 119,376
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 880	$ 2,398
Accrued liabilities	6,532	6,830
Total current liabilities	7,412	9,228
Lease-related obligations	2,923	196
Total liabilities	10,335	9,424
Stockholders' equity:		
Preferred stock, $0.001 par value, 10,000,000 shares authorized at September 30, 2020 and December 31, 2019; no shares issued and outstanding as of September 30, 2020 and December 31, 2019;	—	—
Common stock, $0.001 par value, 200,000,000 shares authorized at September 30, 2020 and December 31, 2019; 62,629,722 and 61,590,013 shares issued and outstanding as of September 30, 2020 and December 31, 2019, respectively	63	62
Additional paid-in capital	783,758	778,693
Accumulated other comprehensive gain, net	33	35
Accumulated deficit	(700,685)	(668,838)
Total stockholders' equity	83,169	109,952
Total liabilities and stockholders' equity	$ 93,504	$ 119,376

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	**2019**	**2020**	**2019**
Revenues:				
Contract revenue	$ 1,591	$ 1,958	$ 4,158	$ 5,752
Licensing revenue	18	-	94	-
Total revenues	1,609	1,958	4,252	5,752
Operating expenses:				
Research and development	10,018	7,453	27,545	34,795
General and administrative	3,151	4,024	9,466	18,022
Acquired in-process research and development	-	65,045	-	65,045
Total operating expenses	13,169	76,522	37,011	117,862
Loss from operations	(11,560)	(74,564)	(32,759)	(112,110)
Other income:				
Interest income and other, net	149	834	912	3,037
Net loss	(11,411)	(73,730)	(31,847)	(109,073)
Other comprehensive loss:				
Unrealized (loss)/gain on debt investments, net	(97)	(36)	(2)	182
Comprehensive loss	$ (11,508)	$ (73,766)	$ (31,849)	$ (108,891)
Per share information:				
Net loss, basic and diluted	$ (0.18)	$ (1.26)	$ (0.51)	$ (2.04)
Weighted-average shares outstanding, basic and diluted	62,242,456	58,457,110	62,009,941	53,519,207

Source: Chimerix, Inc.