Chimerix Reports Second Quarter 2020 Financial Results and Provides Operational Update

August 10, 2020

– Completion of BCV NDA Rolling Submission Planned for Third Quarter 2020 –

– Currently Enrolling Phase 2/3 Study of DSTAT in Patients with COVID-19;
Phase 2 Enrollment Completion Expected in Fourth Quarter –

– Startup Activities for DSTAT Phase 3 AML Study Initiated;
Site Activation Expected Early 2021 –

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

DURHAM, N.C., Aug. 10, 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 second quarter ended June 30, 2020 and provided an operational update.

Mike Sherman, Chief Executive Officer of Chimerix, commented, “Our enthusiasm for the potential of dociparstat sodium (DSTAT) to treat COVID-19 patients continues to grow as new data emerges on the role of high mobility group box 1 (HMGB1) which has recently been correlated with disease severity and survival. DSTAT’s key targets include both HMGB1 and platelet factor 4 (PF4). Inhibition of HMGB1 and PF4 with DSTAT could substantially address the excessive inflammation and coagulation disorders observed in these patients. We are currently enrolling our Phase 2/3 study of DSTAT as a treatment for acute lung injury (ALI) in patients with COVID-19 and expect to complete Phase 2 enrollment in the fourth quarter of 2020. We have also resumed work on our DSTAT program for the treatment of acute myeloid leukemia (AML) and now expect site activation for the Phase 3 study to begin in early 2021.”

Mr. Sherman continued, “With the recent additions of Dr. Allen Melemed as Chief Medical Officer and Caryn Barnett as Vice President of Clinical Operations, we have continued to enhance our strong leadership team. Both executives bring decades of successful drug development expertise to Chimerix as we advance our pipeline.”

“Importantly, we are in the midst of our rolling submission of the New Drug Application (NDA) for the approval of brincidofovir (BCV) as a medical countermeasure for smallpox and expect to complete it by the end of the third quarter. The COVID-19 pandemic has highlighted the importance of preparedness to treat future viral outbreaks, especially those as deadly as smallpox, and we look forward to a possible BCV regulatory approval and a potential procurement contract for the U.S. Strategic National Stockpile (SNS),” concluded Mr. Sherman.

Recent Highlights

- Began rolling NDA submission for the approval of BCV as a medical countermeasure for smallpox
- Initiated enrollment in Phase 2/3 trial of DSTAT in ALI patients with COVID-19

Expected Upcoming Milestones

- Completion of NDA submission of BCV in third quarter 2020
- Completion of enrollment of Phase 2 portion of DSTAT trial in COVID-19 in fourth quarter of 2020
- Initiate Phase 3 AML trial in early 2021
- Potential procurement agreement for BCV prior to FDA decision on smallpox NDA
- FDA decision on BCV smallpox NDA in 2021
- Completion of BCV drug product manufacturing to support a potential shipment to the SNS of up to $100 million in 2021

Second Quarter 2020 Financial Results

Chimerix reported a net loss of $10.0 million, or $0.16 per basic and diluted share, for the second quarter of 2020. During the same period in 2019, Chimerix recorded a net loss of $17.7 million, or $0.35 per basic and diluted share.

Revenues for the second quarter of 2020 were $1.4 million, equal to the same period of 2019.

Research and development expenses decreased to $8.6 million for the second quarter of 2020, compared to $13.8 million for the same period in 2019.

General and administrative expenses decreased to $3.1 million for the second quarter of 2020, compared to $6.3 million for the same period in 2019.

Loss from operations was $10.3 million for the second quarter of 2020, compared to a loss from operations of $18.7 million for the same period in 2019.

Chimerix's balance sheet at June 30, 2020, included $96 million of capital available to fund operations, no debt and approximately 62.2 million outstanding shares of common stock. The Company reaffirms its previous cash balance forecast of approximately $70 million at the end of 2020.

Conference Call and Webcast

Chimerix will host a conference call and live audio webcast to discuss second 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 3334648.

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 drug candidates 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. Inhibition of HMGB1 may be a primary anti-inflammatory target for DSTAT. HMGB1 induces downstream proinflammatory cytokines, including but not limited to, IL-6, TNF-α, monocyte chemoattractant protein-1 (MCP-1) and macrophage inflammatory protein-1α (MIP-1α), all of which are elevated in COVID-19. DSTAT also binds to and inhibits the activity of PF4 which appears to play a significant role in the coagulation disorders observed in severe COVID-19.

A Phase 3 trial protocol to study DSTAT in acute myeloid leukemia has been agreed to with the US Food and Drug Administration (FDA) and site activation is expected in early 2021. BCV is an antiviral drug candidate in development as a medical countermeasure for smallpox. 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, the mechanism of action of DSTAT and its potential in ALI patients with COVID-19; Chimerix's ability to develop DSTAT, including the ongoing Phase 2/3 clinical trial for DSTAT as a potential treatment for ALI associated with COVID-19, and the site activation of the Phase 3 clinical trial for DSTAT for the treatment of AML; Chimerix's ability to submit and/or obtain regulatory approvals for DSTAT and BCV; and the timing and receipt of a potential procurement contract for BCV in smallpox. 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 achieve the endpoints in its clinical trials; risks that DSTAT and BCV 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 associated with entering in to a procurement agreement for BCV on expected terms 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)

	June 30, 2020	December 31, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	$ 53,501	$ 16,901

Short-term investments, available-for-sale	42,449	96,574
Accounts receivable	367	1,233
Prepaid expenses and other current assets	2,578	3,385
Total current assets	98,895	118,093
Property and equipment, net of accumulated depreciation	338	540
Operating lease right-of-use assets	2,414	709
Other long-term assets	26	34
Total assets	$ 101,673	$ 119,376
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,425	$ 2,398
Accrued liabilities	4,811	6,830
Total current liabilities	6,236	9,228
Lease-related obligations	2,302	196
Total liabilities	8,538	9,424
Stockholders' equity:		
Preferred stock, $0.001 par value, 10,000,000 shares authorized at June 30, 2020 and December 31, 2019; no shares issued and outstanding as of June 30, 2020 and December 31, 2019;	—	—
Common stock, $0.001 par value, 200,000,000 shares authorized at June 30, 2020 and December 31, 2019; 62,172,418 and 61,590,013 shares issued and outstanding as of June 30, 2020 and December 31, 2019, respectively	62	62
Additional paid-in capital	782,217	778,693
Accumulated other comprehensive gain, net	130	35
Accumulated deficit	(689,274)	(668,838)
Total stockholders' equity	93,135	109,952
Total liabilities and stockholders' equity	$ 101,673	$ 119,376

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	**2019**	**2020**	**2019**
Revenues:				
Contract revenue	$ 1,396	$ 1,438	$ 2,567	$ 3,794
Licensing revenue	6	-	76	-
Total revenues	1,402	1,438	2,643	3,794
Operating expenses:				
Research and development	8,578	13,827	17,527	27,342
General and administrative	3,110	6,312	6,315	13,998
Total operating expenses	11,688	20,139	23,842	41,340
Loss from operations	(10,286)	(18,701)	(21,199)	(37,546)
Other income:				
Interest income and other, net	270	1,051	763	2,203
Net loss	(10,016)	(17,650)	(20,436)	(35,343)
Other comprehensive loss:				
Unrealized gain on debt investments, net	141	77	95	217
Comprehensive loss	$ (9,875)	$ (17,573)	$ (20,341)	$ (35,126)
Per share information:				
Net loss, basic and diluted	$ (0.16)	$ (0.35)	$ (0.33)	$ (0.69)
Weighted-average shares outstanding, basic and diluted	62,042,778	51,130,104	61,892,407	51,009,935

Source: Chimerix, Inc.