Chimerix Announces Third Quarter 2019 Financial Results and Provides Operational Update

November 5, 2019

– Final Data from Phase 2 Randomized Trial of DSTAT in First-line AML Support Enhanced Durability of Response, Event-free Survival and Overall Survival Benefit –

– End of Phase 2 Meeting for Dociparstat (DSTAT) and Pre-NDA Meeting for Brincidofovir (BCV) Anticipated during First Quarter 2020 –

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

DURHAM, N.C., Nov. 05, 2019 (GLOBE NEWSWIRE) -- Chimerix, Inc. (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, 2019 and provided an operational update.

"The progress we have made over the last several months has positioned us well for the balance of the year and beyond. We have successfully transitioned our clinical pipeline to deliver a number of near-term, value-creating milestones," said Mike Sherman, President and Chief Executive Officer of Chimerix. "As we look toward 2020, we expect to achieve several key milestones, including a meeting with U.S. regulatory authorities to confirm our pivotal study protocol for dociparstat sodium (DSTAT) in first-line acute myeloid leukemia (AML), initiation of that important study mid-year, submission of the marketing application for brincidofovir (BCV) as a medical countermeasure for smallpox, and a potential procurement contract with BARDA to enable the addition of BCV to the U.S. Strategic National Stockpile. Importantly, while there have been several recent approvals of targeted therapies in AML, the overall five-year survival rate of roughly 10% in older patients remains low. With DSTAT, our aim is to meaningfully improve first-line therapy results in order to deliver long-term, durable responses for patients."

Third Quarter and Recent Highlights

Final Analysis of Randomized Trial of DSTAT in Front-line AML Patients

In July, Chimerix entered into a License and Development Agreement with Cantex Pharmaceuticals, Inc. (Cantex) pursuant to which Chimerix acquired exclusive worldwide rights to develop and commercialize DSTAT for any and all uses. DSTAT is a glycosaminoglycan biologic derived from porcine heparin that has low anticoagulant activity, but retains the ability to inhibit activities of several key proteins implicated in the retention and viability of AML blasts and leukemic stem cells in the bone marrow during chemotherapy (e.g., CXCL12, selectins, HMGB1). DSTAT has received Fast Track and Orphan Drug Designations from the U.S. Food and Drug Administration for the treatment of AML.

In October 2019, Chimerix presented final results from the recently completed Phase 2b, randomized controlled trial of DSTAT in AML. The study evaluated DSTAT (4 mg/kg intravenous (IV) bolus followed by either 0.125 or 0.25 mg/kg/hr continuous IV infusion for 7 days) in combination with standard 7+3 chemotherapy versus chemotherapy alone in 75 subjects, greater than 60 years of age, with newly diagnosed AML. An analysis of the intent-to-treat (ITT) population in this study indicated that patients receiving DSTAT 0.25 mg/kg/hr exhibited improved hazard ratios for event-free survival (EFS, 0.67), overall survival (OS, 0.68) and relapse free-survival (RFS, 0.45) when compared to control patients. Complete response rates (CR/CRi) were similar between the arms. An analysis of subjects meeting the likely target inclusion criteria for the Phase 3 study, which excludes patients with favorable cytogenetics or secondary AML, showed improved observed hazard ratios for DSTAT 0.25 mg/kg/hr versus control for EFS (0.58), OS (0.51), and RFS (0.39).

Combination treatment with 7+3 chemotherapy and DSTAT did not show significant added toxicity at the 0.125 or 0.25 mg/kg/hr doses. The most common serious adverse event in the DSTAT arm was febrile neutropenia. DSTAT also showed signs of accelerating platelet and neutrophil recovery following chemotherapy, consistent with the reported DSTAT inhibition of platelet factor 4, a negative regulator of platelet production that impairs platelet recovery following chemotherapy.

Chimerix plans to initiate a Phase 3 clinical trial of DSTAT for the treatment of AML in mid-2020 subject to discussions with FDA in early 2020.

BCV for Smallpox

Chimerix intends to conduct a pre-NDA meeting with the FDA in the first quarter of 2020 and submit marketing applications for BCV in mid-2020, contingent upon final audited results of the animal efficacy studies and the finalization of animal PK analysis necessary to bridge to a recommended human dose. Earlier this year Chimerix reported statistically significant and clinically meaningful reduction in mortality from GLP mousepox and rabbitpox studies. Data from these studies are intended to address the requirement under the FDA's Animal Efficacy Rule for two different animal models of efficacy.

Chimerix is collaborating with the Biomedical Advanced Research and Development Authority (BARDA) for the development of BCV as a potential medical countermeasure for smallpox. This rule allows for testing of investigational drugs in animal models to support the effectiveness of the drug in diseases for which human clinical studies are not ethical or feasible.

Exclusive Global License Agreement with SymBio Pharmaceuticals for BCV

In September, Chimerix entered into an exclusive global license agreement with SymBio Pharmaceuticals, Ltd. (SymBio), under which SymBio has exclusively licensed the worldwide rights to develop, manufacture and commercialize BCV in all human indications, excluding the prevention and

treatment of orthopoxviruses, including smallpox. Moving forward, SymBio will be responsible for all future development, commercialization and manufacturing associated with BCV in those licensed indications.

Under the terms of the agreement, Chimerix received an upfront payment of $5 million with the potential to receive future clinical, regulatory and commercial milestone payments of up to $180 million. In addition, Chimerix is eligible to receive low double-digit royalty payments on net sales of BCV worldwide.

Third Quarter 2019 Financial Results

Chimerix reported a net loss of $73.7 million, or $1.26 per basic and diluted share, for the third quarter of 2019. During the same period in 2018, Chimerix recorded a net loss of $16.1 million, or $0.33 per basic and diluted share.

Revenues for the third quarter of 2019 increased to $2.0 million, compared to $0.4 million for the same period in 2018.

Research and development expenses decreased to $7.5 million for the third quarter of 2019, compared to $11.9 million for the same period in 2018.

General and administrative expenses decreased to $4.0 million for the third quarter of 2019, compared to $5.2 million for the same period in 2018.

Chimerix recorded acquired-in-process research and development expenses of $65.0 million for the third quarter of 2019 related to the Cantex transaction.

Loss from operations was $74.6 million for the third quarter of 2019, compared to a loss from operations of $16.7 million for the same period in 2018.

Chimerix's balance sheet at September 30, 2019 included $116.7 million of capital available to fund operations, no debt, and approximately 61.4 million outstanding shares of common stock. The Company reaffirms its previous guidance of approximately $110 million in cash and cash equivalents at the end of 2019.

Conference Call and Webcast

Chimerix will host a conference call and live audio webcast to discuss third quarter 2019 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 1693898.

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

Dociparstat sodium is a potential first-in-class glycosaminoglycan biologic derived from porcine heparin that has low anticoagulant activity but retains the ability to inhibit activities of several key proteins implicated in the retention and viability of AML blasts and leukemic stem cells in the bone marrow during chemotherapy (e.g., CXCL12, selectins, HMGB1). Mobilization of AML blasts and leukemic stem cells from the bone marrow has been associated with enhanced chemosensitivity and may be a primary mechanism accounting for the observed increases in EFS and OS in Phase 2 with DSTAT versus placebo. Randomized Phase 2 data suggest that DSTAT may also accelerate platelet recovery post-chemotherapy via inhibition of platelet factor 4, a negative regulator of platelet production that impairs platelet recovery following chemotherapy. BCV is a lipid conjugate DNA polymerase inhibitor 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, Chimerix's ability to deliver near-term, value-creating milestones; the potential benefits to be derived from the License and Development Agreement with SymBio Pharmaceuticals or Cantex Pharmaceuticals, including any statements related to DSTAT; Chimerix's ability to develop disease modifying and potentially curative treatments for diseases, including AML and smallpox; and, Chimerix's ability to submit for marketing authorization or enter into a procurement contract for BCV as a medical countermeasure. 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 benefits of the agreements with Cantex or SymBio may never be realized; risks that DSTAT or BCV may not obtain regulatory approval from the FDA or such approval may be delayed or conditioned; risks that development activities related to DSTAT or BCV may not be completed on time or at all; Chimerix's reliance on a sole source third-party manufacturers for drug supply; risks that ongoing or future clinical trials may not be successful or replicate previous clinical trial results, or may not be predictive of real-world results or of results in subsequent clinical 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; risks related to procurement of brincidofovir for the treatment of smallpox 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.

CONTACT:

Investor Relations:
Michelle LaSpaluto
919-972-7115
ir@chimerix.com

Will O'Connor

Stern Investor Relations
212-362-1200
will@sternir.com

CHIMERIX, INC.
CONSOLIDATED BALANCE SHEETS
(in thousands, except share and per share data)
(unaudited)

	September 30, 2019	December 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	$ 19,349	$ 81,106
Short-term investments, available-for-sale	97,366	105,424
Accounts receivable	1,822	330
Prepaid expenses and other current assets	7,432	2,598
Total current assets	125,969	189,458
Property and equipment, net of accumulated depreciation	910	1,210
Operating lease right-of-use assets	836	-
Other long-term assets	36	46
Total assets	$ 127,751	$ 190,714
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 3,477	$ 4,691
Accrued liabilities	11,957	8,275
Total current liabilities	15,434	12,966
Lease-related obligations	369	144
Total liabilities	15,803	13,110
Stockholders' equity:		
Preferred stock, $0.001 par value, 10,000,000 shares authorized at September 30, 2019 and December 31, 2018; no shares issued and outstanding as of September 30, 2019 and December 31, 2018	—	—
Common stock, $0.001 par value, 200,000,000 shares authorized at September 30, 2019 and December 31, 2018; 61,382,263 and 50,735,279 shares issued and outstanding as of September 30, 2019 and December 31, 2018, respectively	61	51
Additional paid-in capital	777,133	733,907
Accumulated other comprehensive loss, net	89	(92)
Accumulated deficit	(665,335)	(556,262)
Total stockholders' equity	111,948	177,604
Total liabilities and stockholders' equity	$ 127,751	$ 190,714

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,	
	2019	2018	2019	2018
Contract revenue	$ 1,958	$ 369	$ 5,752	$ 2,352
Operating expenses:				
Research and development	7,453	11,892	34,795	39,963
General and administrative	4,024	5,187	18,022	18,575
Acquired in-process research and development	65,045	-	65,045	-
Total operating expenses	76,522	17,079	117,862	58,538

Loss from operations	(74,564)	(16,710)	(112,110)	(56,186)
Other (expense) income:				
Interest income and other, net	834	631	3,037	1,668
Net loss	(73,730)	(16,079)	(109,073)	(54,518)
Other comprehensive loss:				
Unrealized (loss) gain on debt investments, net	(36)	180	182	302
Comprehensive loss	$ (73,766)	$ (15,899)	$ (108,891)	$ (54,216)
Per share information:				
Net loss, basic and diluted	$ (1.26)	$ (0.33)	$ (2.04)	$ (1.14)
Weighted-average shares outstanding, basic and diluted	58,457,110	48,172,354	53,519,207	47,875,895

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Source: Chimerix, Inc.