Chimerix Reports Fourth Quarter and Year End 2019 Financial Results and Provides Operational Update

February 25, 2020

- Successful DSTAT End of Phase 2 Meeting with FDA Confirms Phase 3 Readiness; First Patient Visit Expected mid-2020 in 1L AML -

- Brincidofovir pre-NDA Meeting Scheduled with FDA, on Track for mid-2020 NDA Filing -

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

DURHAM, N.C., Feb. 25, 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 fourth quarter and full-year ended December 31, 2019 and provided an operational update.

"The transformation and progress we made in 2019 has laid the foundation for Chimerix to achieve a number of value-creating milestones in 2020," said Mike Sherman, Chief Executive Officer of Chimerix. "The team has continued to execute extremely well as we plan to file our first New Drug Application (NDA) for brincidofovir (BCV) as a medical countermeasure for smallpox and advance our promising dociparstat sodium (DSTAT) program into pivotal Phase 3 clinical development as a front-line treatment for acute myeloid leukemia (AML)."

Fourth Quarter and Recent Highlights

Phase 3 Pivotal Trial of DSTAT in Front-line AML Patients

Chimerix recently conducted an end of Phase 2 meeting with the U.S. Food and Drug Administration (FDA) related to the Company's development of DSTAT in AML. Following that meeting, Chimerix incorporated FDA's feedback on key elements of the Phase 3 clinical trial and has since submitted a full protocol for final FDA review. Chimerix plans to initiate a Phase 3 trial mid-year of DSTAT in combination with standard chemotherapy (cytarabine plus anthracycline, or "7+3") in newly diagnosed AML patients.

The proposed Phase 3 trial will be a randomized, double-blind trial of approximately 570 newly diagnosed AML patients. The trial will include patients 60 years of age or older who have an intermediate or adverse genetic risk profile. It will also include patients between 18 and 60 years of age who have an adverse genetic risk profile. Patients will be randomized 1:1 to receive DSTAT in combination with standard of care cytarabine plus anthracycline (7+3) induction and cytarabine consolidation chemotherapy or to receive standard of care (7+3) induction and consolidation chemotherapy alone. Patients with FLT-3 mutations will be allowed in the study and will be eligible to receive midostaurin.

The primary endpoint of the proposed trial will be overall survival (OS). In addition, FDA has indicated that event-free survival (EFS), using complete response with hematologic recovery to define induction success (CR), is acceptable as an endpoint for regulatory approval. Other endpoints to be evaluated in the proposed trial include minimal residual disease (MRD), relapse-free survival (RFS), time to hematologic recovery, and induction response.

In order to supplement the previously reported data from the pilot and Phase 2 trials and provide additional evidence of DSTAT's mechanism of action, the proposed Phase 3 trial includes an early assessment of comparative CR and MRD rates among the first 80 evaluable patients. This data is expected to be unblinded, reported publicly, and available for ongoing analysis of later endpoints. Prior to potential unblinding, this data will be reviewed by an independent Data Monitoring Committee (DMC). The DMC will have the discretion to maintain blinding of the data from this early assessment in the event the DSTAT arm shows exceptional advantages to the control arm on CR and/or MRD, at certain pre-specified thresholds, which would allow inclusion of these patients in the final analysis.

The Company expects to incur approximately $15 million in clinical trial expenses up to and including this early assessment.

BCV as a Medical Countermeasure for Smallpox

In January, Chimerix presented data in support of BCV as a potential treatment for smallpox at the 2020 American Society for Microbiology (ASM) Biothreats Meeting in Arlington, Virginia. The presentation highlighted independent experiments performed in two lethal animal models of smallpox. In these studies, either rabbits or mice were inoculated with rabbitpox or ectromelia (mousepox) virus, respectively, to determine the survival benefit conferred by BCV treatment in animals acutely infected with these orthopoxviruses. Animals were randomized to receive either placebo or BCV at varying time intervals post infection. In both studies, animals that received BCV, even when administered late post-infection, demonstrated a statistically significant survival advantage relative to placebo.

Data from these studies are intended to address the requirement under the FDA 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 the efficacy of investigational drugs in animal models for diseases which cannot be evaluated in human clinical studies.

In cooperation with BARDA, Chimerix has scheduled a pre-NDA meeting with FDA to review the final efficacy and safety data in preparation to submit an NDA. Pending the outcome of this meeting, Chimerix intends to submit a BCV NDA for smallpox in mid-2020. The Company's operating and manufacturing plan assumes entering into a procurement contract with BARDA in 2020 and preparation for delivery of BCV into the Strategic National

Stockpile in 2021.

Fourth Quarter 2019 Financial Results

Chimerix's balance sheet at December 31, 2019 included $113.5 million of capital available to fund operations, no debt, and approximately 61.6 million outstanding shares of common stock.

Chimerix reported a net loss of $3.5 million, or $0.06 per basic and diluted share, for the fourth quarter of 2019. During the same period in 2018, Chimerix recorded a net loss of $15.0 million, or $0.29 per basic and diluted share.

Revenues for the fourth quarter of 2019 increased to $6.8 million, compared to $4.9 million for the same period in 2018.

Research and development expenses decreased to $7.5 million for the three-month period ended December 31, 2019, compared to $15.3 million for the same period in 2018.

General and administrative expenses decreased to $3.1 million for the fourth quarter of 2019, compared to $5.0 million for the same period in 2018.

Loss from operations was $3.9 million for the fourth quarter of 2019, compared to a loss from operations of $15.4 million for the same period in 2018.

Full Year 2019 Financial Results

Chimerix reported a net loss of $112.6 million, or $2.03 per basic and diluted share, for the year ended December 31, 2019. For the year ended December 31, 2018, Chimerix recorded a net loss of $69.5 million, or $1.43 per basic and diluted share.

Revenues for 2019 increased to $12.5 million, compared to $7.2 million in 2018.

Research and development expenses decreased to $42.3 million for the year ended December 31, 2019, compared to $55.2 million for the year ended December 31, 2018.

General and administrative expenses decreased to $21.2 million for the year ended December 31, 2019, compared to $23.6 million for the year ended December 31, 2018.

Chimerix recorded acquired-in-process research and development expenses of $65.0 million for the year ended December 31, 2019 related to the Cantex transaction.

Loss from operations was $116.0 million for the year ended December 31, 2019, compared to a loss from operations of $71.6 million for the year ended December 31, 2018.

Conference Call and Webcast

Chimerix will host a conference call and live audio webcast to discuss fourth quarter and full-year 2019 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 1397800.

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

Dociparstat sodium is a potential first-in-class glycosaminoglycan compound 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, elastase). 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 survival endpoints 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 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, Chimerix's ability to develop DSTAT and BCV, including the initiation of a Phase 3 clinical trial for DSTAT; Chimerix's ability to submit and/or obtain regulatory approvals for DSTAT and BCV; and Chimerix's ability to 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 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 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; risks related to procurement of BCV 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.

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

	December 31, 2019	December 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	$ 16,901	$ 81,106
Short-term investments, available-for-sale	96,574	105,424
Accounts receivable	1,233	330
Prepaid expenses and other current assets	3,385	2,598
Total current assets	118,093	189,458
Property and equipment, net of accumulated depreciation	540	1,210
Operating lease right-of-use assets	709	-
Other long-term assets	34	46
Total assets	$ 119,376	$ 190,714
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,398	$ 4,691
Accrued liabilities	6,830	8,275
Total current liabilities	9,228	12,966
Lease-related obligations	196	144
Total liabilities	9,424	13,110
Stockholders' equity:		
Preferred stock, $0.001 par value, 10,000,000 shares authorized at December 31, 2019 and 2018; no shares issued and outstanding as of December 31, 2019 and 2018	-	-
Common stock, $0.001 par value, 200,000,000 shares authorized at December 31, 2019 and 2018; 61,590,013 and 50,735,279 shares issued and outstanding as of December 31, 2019 and 2018, respectively	62	51
Additional paid-in capital	778,693	733,907
Accumulated other comprehensive loss, net	35	(92)
Accumulated deficit	(668,838)	(556,262)
Total stockholders' equity	109,952	177,604
Total liabilities and stockholders' equity	$ 119,376	$ 190,714

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,	
	2019	2018	2019	2018
Revenues:				
Contract revenue	$ 1,852	$ 4,864	$ 7,604	$ 7,216
Licensing revenue	4,915	-	4,915	-
Total revenues	6,767	4,864	12,519	7,216
Operating expenses:				

Research and development	7,493	15,276	42,288	55,239
General and administrative	3,147	5,007	21,169	23,582
Acquired in-process research and development	-	-	65,045	-
Total operating expenses	10,640	20,283	128,502	78,821
Loss from operations	(3,873)	(15,419)	(115,983)	(71,605)
Other income:				
Interest income and other, net	370	463	3,407	2,131
Net loss	(3,503)	(14,956)	(112,576)	(69,474)
Other comprehensive loss:				
Unrealized (loss) gain on investments, net	(55)	569	127	871
Comprehensive loss	$ (3,558)	$ (14,387)	$ (112,449)	$ (68,603)
Per share information:				
Net loss, basic and diluted	$ (0.06)	$ (0.29)	$ (2.03)	$ (1.43)
Weighted-average shares outstanding, basic and diluted	61,385,616	50,722,655	55,501,973	48,593,435

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Source: Chimerix, Inc.