Chimerix Announces Second Quarter 2019 Financial Results and Operational Update

August 8, 2019

Pipeline Transformed with Acquisition of Global Rights to Late Stage Oncology Asset (CX-01) with Fast Track and Orphan Drug Designation

Phase 3 Trial of CX-01 in Front-Line Acute Myeloid Leukemia Planned to Initiate in Mid 2020

Finalizing Animal Studies of Brincidofovir as Smallpox Medical Countermeasure for Planned NDA

DURHAM, N.C., Aug. 08, 2019 (GLOBE NEWSWIRE) -- Chimerix (NASDAQ:CMRX), today reported financial results for the second quarter ended June 30, 2019 and provided an operational update.

"We were delighted to announce our acquisition of exclusive worldwide rights to a Phase 3 ready program in oncology. We are particularly pleased to have so rapidly sourced this promising oncology product candidate, as it allows us to focus our efforts on moving quickly into Phase 3 development of CX-01 in front-line therapy for acute myeloid leukemia (AML), an area where there are limited front-line treatment options. CX-01 has shown compelling activity across multiple endpoints in first-line AML patients in combination with back-bone chemotherapy regimen, whereas most recent advances in AML have been in genetically defined patient populations, or in relapsed/refractory patients," stated Mike Sherman, Chief Executive Officer of Chimerix. "The mechanisms of action for CX-01 also create the opportunity to develop the therapy for the treatment of a number of other challenging hematologic malignancies, where there are significant market opportunities."

"In addition, we are looking forward to filing a New Drug Application (NDA) for brincidofovir next year for the treatment of smallpox, as we believe this offers a significant opportunity to be an important medical countermeasure for our national strategic stockpile, and potential non-dilutive funding for the company," continued Mr. Sherman.

Second Quarter and Recent Highlights

CX-01 for Acute Myeloid Leukemia

In July, Chimerix announced the completion of an exclusive worldwide license of CX-01 from Cantex Pharmaceuticals, Inc. Chimerix intends to move quickly into Phase 3 development of CX-01 for the treatment of Acute Myeloid Leukemia (AML) in the first-line setting.

CX-01 (dociparstat sodium) is an investigational product derived from unfractionated heparin with very low anticoagulant activity. CX-01 targets key protein pathways important for AML blast cell migration to the bone marrow and retention of these cells in the marrow where they are protected from chemotherapy. CX-01 also binds with proteins involved in chemotherapy resistance and the delay in platelet recovery after chemotherapy. Together, these activities are understood to sensitize AML blasts to chemotherapy and improve clinical responses.

Chimerix plans to initiate a Phase 3 clinical trial of CX-01 for the treatment of AML in mid-2020 subject to discussions with FDA.

CX-01 has received Fast Track and Orphan Drug Designations from the U.S. Food and Drug Administration for the treatment of AML.

Brincidofovir (BCV) for Smallpox

Data from Chimerix's completed mouse ectromelia and rabbitpox studies are intended to address the requirement under the FDA's Animal Efficacy Rule for two different animal models of efficacy. Positive overall survival results in both animal models were announced earlier this year. Contingent upon final audited results of the animal efficacy studies, along with finalizing the animal PK analysis necessary to bridge to a recommended human dose, Chimerix intends to submit marketing applications in 2020.

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 in which human clinical studies are not ethical or feasible.

Second Quarter 2019 Financial Results

Chimerix reported a net loss of $17.7 million, or $0.35 per basic and diluted share, for the second quarter of 2019. During the same period in 2018, Chimerix recorded a net loss of $18.6 million, or $0.39 per basic and diluted share.

Revenues for the second quarter of 2019 increased to $1.4 million, compared to $1.2 million for the same period in 2018.

Research and development expenses increased to $13.8 million for the second quarter of 2019, compared to $13.7 million for the same period in 2018.

General and administrative expenses decreased to $6.3 million for the second quarter of 2019, compared to $6.7 million for the same period in 2018.

Loss from operations was $18.7 million for the second quarter of 2019, compared to a loss from operations of $19.2 million for the same period in 2018.

As of June 30, 2019, Chimerix had approximately $158.4 million of capital available to fund operations. The Company has no debt and approximately

51.2 million outstanding shares of common stock. Following the recent transaction with Cantex Pharmaceuticals, Chimerix expects to end 2019 with approximately $105 million in capital to fund operations. This amount reflects payments related to the upfront payment associated with the in-license of CX-01, development costs of CX-01, and the Company's previously announced corporate restructuring expenses of $3.2 million related to the close-out of oral and intravenous BCV clinical trials and $3.3 million in severance costs.

About CX-01

CX-01 (dociparstat sodium) is an investigational product derived from unfractionated heparin with very low anticoagulant activity. CX-01 targets key protein pathways important for AML blast cell migration to the bone marrow and retention of these cells in the marrow where they are protected from chemotherapy. CX-01 also binds with proteins involved in chemotherapy resistance and the delay in platelet recovery after chemotherapy. Together, these activities are understood to sensitize AML blasts to chemotherapy and improve clinical responses. These mechanisms of action support the potential for development in myelodysplastic syndrome, multiple myeloma, and lymphomas.

About Brincidofovir

Chimerix's antiviral product candidate, brincidofovir, is a nucleotide analog that has activity against all five families of DNA viruses that affect humans, including the herpesviruses and adenoviruses. Brincidofovir has a high barrier to resistance, no myelosuppression and a low risk of nephrotoxicity. Brincidofovir has received Fast Track designation from the FDA and Orphan Medicinal Product Designation from the European Commission for adenovirus, cytomegalovirus, and smallpox. Brincidofovir has Orphan Drug Designation for smallpox.

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. CX-01 (dociparstat sodium) is an investigational product targeting multiple proteins involved in cancer cell resistance to chemotherapy under development for the treatment of acute myeloid leukemia and other hematologic malignancies. Brincidofovir (BCV, CMX001) is an anti-viral 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 includes 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 submission of marketing applications for BCV for the treatment of smallpox, the potential benefits to be derived from the license agreement with Cantex Pharmaceuticals, including statements related to the activity profile and opportunities for potential development of CX-01; Chimerix's ability to develop disease modifying and potentially curative treatments for diseases, including AML. 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 agreement with Cantex may never be realized; risks that our product candidates may not obtain regulatory approval from the FDA or such approval may be delayed or conditioned; risks that development activities related to our product candidates may not be completed on time or at all; Chimerix's reliance on sole source third-party manufacturers for our product candidates; 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 product candidates; risks that our product candidates 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, 2019	December 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	$ 21,644	$ 81,106
Short-term investments, available-for-sale	136,755	105,424
Accounts receivable	774	330
Prepaid expenses and other current assets	2,200	2,598
Total current assets	161,373	189,458

Property and equipment, net of accumulated depreciation	1,054	1,210
Operating lease right-of-use assets	969	-
Other long-term assets	45	46
Total assets	$ 163,441	$ 190,714
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,832	$ 4,691
Accrued liabilities	11,954	8,275
Total current liabilities	13,786	12,966
Lease-related obligations	537	144
Total liabilities	14,323	13,110
Stockholders' equity:		
Preferred stock, $0.001 par value, 10,000,000 shares authorized at June 30, 2019 and December 31, 2018; no shares issued and outstanding as of June 30, 2019 and December 31, 2018	—	—
Common stock, $0.001 par value, 200,000,000 shares authorized at June 30, 2019 and December 31, 2018; 51,230,916 and 50,735,279 shares issued and outstanding as of June 30, 2019 and December 31, 2018, respectively	51	51
Additional paid-in capital	740,547	733,907
Accumulated other comprehensive loss, net	125	(92)
Accumulated deficit	(591,605)	(556,262)
Total stockholders' equity	149,118	177,604
Total liabilities and stockholders' equity	$ 163,441	$ 190,714

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,	
	2019	**2018**	**2019**	**2018**
Contract revenue	$ 1,438	$ 1,193	$ 3,794	$ 1,983
Operating expenses:				
Research and development	13,827	13,712	27,342	28,071
General and administrative	6,312	6,650	13,998	13,388
Total operating expenses	20,139	20,362	41,340	41,459
Loss from operations	(18,701)	(19,169)	(37,546)	(39,476)
Other (expense) income:				
Unrealized loss on equity investment	(22)	(78)	(30)	(212)
Interest income and other, net	1,073	634	2,233	1,249
Net loss	(17,650)	(18,613)	(35,343)	(38,439)
Other comprehensive loss:				
Unrealized gain on debt investments, net	77	225	217	122
Comprehensive loss	$ (17,573)	$ (18,388)	$ (35,126)	$ (38,317)
Per share information:				
Net loss, basic and diluted	$ (0.35)	$ (0.39)	$ (0.69)	$ (0.81)
Weighted-average shares outstanding, basic and diluted	51,130,104	47,811,552	51,009,935	47,725,209

CHIMERIX

Source: Chimerix, Inc.