Chimerix Announces Fourth Quarter and Full Year 2018 Financial Results

March 5, 2019

– Reports Positive Preliminary Top-line Data from Second Rabbitpox Study –

– Type C Meeting Requested with FDA Regarding Virologic Endpoint –

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

DURHAM, N.C., March 05, 2019 (GLOBE NEWSWIRE) -- Chimerix (NASDAQ:CMRX), a biopharmaceutical company developing novel antivirals to address unmet medical needs, today reported financial results and provided a corporate update for the fourth quarter and full-year ended December 31, 2018.

“During 2018 and in recent weeks, we made important strides towards advancing our antiviral pipeline across a number of important infectious disease indications. In particular, we were very pleased with the preliminary data from our rabbitpox study, which showed statistically significant survival benefit in brincidofovir (BCV) treated rabbits,” said Garrett Nichols, M.D., M.S., Chief Medical Officer of Chimerix.

“In addition, we continue to advance brincidofovir for the treatment of adenovirus (AdV) in our AdAPT study, with the goal of completing this trial as quickly as possible given the high mortality associated with this disease. We have, however, faced delays in enrollment of the trial, and will provide an update on projected enrollment completion in mid-2019. We have also submitted a request for a Type C meeting with the U.S. Food and Drug Administration (FDA) to discuss adenoviral burden, the primary endpoint for AdAPT, as a potential surrogate marker for mortality,” concluded Dr. Nichols.

Program Updates

BCV for Smallpox

Today, Chimerix reports preliminary top-line results from the in-life portion of our second rabbitpox efficacy study conducted under the FDA Animal Efficacy Rule.

The study was designed to determine the effect of administering BCV to animals at certain times (3, 4, 5 or 6 days) after infection with the rabbitpox virus. Based on these preliminary findings, the study met its primary endpoint. The top-line survival results are as follows:

	BCV treatment 3 days post-infection	**BCV treatment 4 days post-infection**	**BCV treatment 5 days post-infection**	**BCV treatment 6 days post-infection**	**No treatment (placebo)**
Overall Survival	29/29 (100%)	26/29 (90%)	20/29 (69%)	20/29 (69%)	8/28 (29%)
P-value vs. Placebo	<0.0001	<0.0001	0.0014	0.0014	-

Data from this study are consistent with those reported from the Company’s first pivotal rabbitpox study, conducted in 2015.

In February 2019, Chimerix initiated a pivotal study in the mouse ectromelia model, which constitutes the second animal model as required by the Animal Efficacy Rule. Data from this study are anticipated later this year. Subject to continued positive data, the Company expects to submit marketing applications for smallpox in 2020.

Oral BCV

In 2018, the AdAPT study faced regulatory and site initiation delays. Based on a thorough re-evaluation of current screening and enrollment rates, Chimerix now projects that enrollment in the AdAPT study will be substantially delayed beyond 2019. While some recently initiated sites are historically more active in transplantation, the Company continues to evaluate strategies to accelerate the time to completion of the study, including opening further AdAPT sites, and possibly re-considering the targeted number of patients for full enrollment. The Company plans to provide an update on AdAPT enrollment in mid-2019.

The AdAPT study is targeting enrollment of 141 pediatric allogeneic HCT recipients with confirmed AdV infection. Patients are randomized 2:1 to receive short-course oral BCV or local standard-of-care (SOC) treatment at approximately 40 sites in Europe and the United States. The primary endpoint of the study is a comparison of the average AdV viral burden (as measured by AdV DNA levels in blood) over 16 weeks in subjects treated with short-course oral BCV versus those who receive local SOC.

IV BCV

Sites in the US and Europe continue to open for enrollment in our IV BCV Phase 2 studies in adult allo-HCT recipients with AdV. Similar to Adapt, studies 210 and 211 have faced regulatory and site initiation delays. Chimerix also plans to provide a study update in mid-2019. These studies are the first-in-patient studies to demonstrate the safety and tolerability and pharmacokinetic profile of multiple doses of IV BCV in adult transplant recipients with AdV infection. These studies have the potential to show what dose of IV BCV is associated with antiviral activity against AdV and could also provide data on other viral infections.

AdVance U.S. Survey

Chimerix presented results of the AdVance U.S. survey showing that pediatric centers routinely screen for AdV and are likely to have a pre-emptive AdV treatment approach. These findings were presented at the 2019 Transplantation and Cellular Therapy (TCT) Meetings of the American Society for Blood and Marrow Transplantation (ASBMT) and Center for International Blood and Marrow Transplant Research (CIBMTR). The survey examined current practices in the screening and treatment of AdV infection in pediatric and adult allogeneic hematopoietic cell transplant (allo-HCT) recipients in the United States. Twenty-one centers were surveyed, comprising 15 pediatric and 6 adult centers across the U.S.

Oral BCV Decreased HHV-6 Viremia After HCT

Also at TCT, Chimerix presented an analysis of the effect of oral BCV on the occurrence of HHV-6 viremia in a subset of allogeneic HCT recipients from a previously conducted Phase 3 study. Subjects selected for HHV-6 testing were those who did not have HHV-6 viremia at baseline, were randomized within 2 weeks following transplant and who received at least 6 doses of BCV or placebo (PBO) within the first 3 weeks after randomization. Both the magnitude and frequency of HHV-6 viremia were lower in BCV recipients: 15% of BCV subjects versus 31% of PBO subjects had detectable HHV-6 viremia within 6 weeks after HCT. In addition, both rash (9% of BCV recipients vs. 26% of PBO recipients) and HHV-6 encephalitis (none on BCV, 1 case on PBO) were less common on BCV, supporting further investigation of BCV as preventative treatment to reduce the incidence and severity of dsDNA viruses after HCT, including HHV-6.

Fourth Quarter 2018 Financial Results

Chimerix's balance sheet at December 31, 2018 included $186.5 million of capital available to fund operations, no debt, and approximately 50.7 million outstanding shares of common stock.

Chimerix reported a net loss of $15.0 million, or $0.29 per basic and diluted share, for the fourth quarter of 2018. During the same period in 2017, Chimerix recorded a net loss of $19.2 million, or $0.41 per basic and diluted share.

Revenues for the fourth quarter of 2018 increased to $4.9 million, compared to $1.8 million for the same period in 2017.

Research and development expenses were $15.3 million for the three-month period ended December 31, 2018, and $12.9 million for the same period in 2017.

General and administrative expenses decreased to $5.0 million for the fourth quarter of 2018, compared to $7.6 million for the same period in 2017.

Loss from operations was $15.4 million for the fourth quarter of 2018, compared to a loss from operations of $18.7 million for the same period in 2017.

Full Year 2018 Financial Results

Chimerix reported a net loss of $69.5 million, or $1.43 per basic and diluted share, for the year ended December 31, 2018. For the year ended December 31, 2017, Chimerix recorded a net loss of $71.0 million, or $1.51 per basic and diluted share.

Revenues for 2018 increased to $7.2 million, compared to $4.5 million in 2017.

Research and development expenses were $55.2 million for the year ended December 31, 2018, compared to $49.4 million for the year ended December 31, 2017.

General and administrative expenses decreased to $23.6 million for the year ended December 31, 2018, compared to $27.1 million for the year ended December 31, 2017.

Loss from operations was $71.6 million for the year ended December 31, 2018, compared to a loss from operations of $72.1 million for the year ended December 31, 2017.

Interest income and other, net were $2.5 million for the year ended December 31, 2018, compared to interest income and other, net of $2.3 million for the year ended December 31, 2017.

Today's Conference Call and Webcast

Chimerix will host a conference call and live audio webcast to discuss fourth quarter and full year 2018 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 5793148.

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 Brincidofovir

Chimerix's lead product candidate, brincidofovir, is a nucleotide analog that has antiviral 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 biopharmaceutical company dedicated to discovering, developing and commercializing medicines that improve outcomes for immunocompromised patients. Brincidofovir (BCV, CMX001) uses Chimerix's proprietary lipid conjugate. For further information, please visit Chimerix's 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, uncertainties and other factors, including the possibility our current or future clinical trials of brincidofovir may not be successful, that FDA and other regulatory authorities may not approve brincidofovir or brincidofovir-based regimens, and that marketing approvals, if granted, may have significant limitations on their use. As a result, brincidofovir may never be successfully commercialized. In addition, Chimerix may be unable to file for regulatory approval for brincidofovir with other regulatory authorities. Similar risks and uncertainties apply to the Company's development of CMX521.These risks, uncertainties and other factors could cause actual results to differ materially from those expressed or implied by such forward-looking statements. Risks are described more fully in the Company's filings with the Securities and Exchange Commission, including without limitation the Company's most recent Annual Report on Form 10-K and other documents subsequently filed with or furnished to the Securities and Exchange Commission. All forward-looking statements contained in this press release speak only as of the date on which they were made. The Company undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

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

	December 31, 2018	December 31, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	$ 81,106	$ 18,548
Short-term investments, available-for-sale	105,424	132,972
Accounts receivable	330	1,682
Prepaid expenses and other current assets	2,598	3,331
Total current assets	189,458	156,533
Long-term investments	-	76,731
Property and equipment, net of accumulated depreciation	1,210	1,894
Other long-term assets	46	72
Total assets	$ 190,714	$ 235,230
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 4,691	$ 3,812
Accrued liabilities	8,275	9,384
Total current liabilities	12,966	13,196
Lease-related obligations	144	224
Total liabilities	13,110	13,420
Stockholders' equity:		
Preferred stock, $0.001 par value, 10,000,000 shares authorized at December 31, 2018 and 2017; no shares issued and outstanding as of December 31, 2018 and 2017	—	—
Common stock, $0.001 par value, 200,000,000 shares authorized at December 31, 2018 and 2017; 50,735,279 and 47,505,532 shares issued and outstanding as of December 31, 2018 and 2017, respectively	51	47
Additional paid-in capital	733,907	709,514
Accumulated other comprehensive loss, net	(92)	(963)

Accumulated deficit	(556,262)	(486,788)
Total stockholders' equity	177,604	221,810
Total liabilities and stockholders' equity	$ 190,714	$ 235,230

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,	
	2018	**2017**	**2018**	**2017**
Contract revenue	$ 4,864	$ 1,844	$ 7,216	$ 4,494
Operating expenses:				
Research and development	15,276	12,913	55,239	49,448
General and administrative	5,007	7,618	23,582	27,148
Total operating expenses	20,283	20,531	78,821	76,596
Loss from operations	(15,419)	(18,687)	(71,605)	(72,102)
Other (expense) income:				
Unrealized loss on equity investment	(37)	(1,160)	(348)	(1,160)
Interest income and other, net	500	609	2,479	2,278
Net loss	(14,956)	(19,238)	(69,474)	(70,984)
Other comprehensive loss:				
Unrealized gain (loss) on investments, net	569	518	871	(523)
Comprehensive loss	$ (14,387)	$ (18,720)	$ (68,603)	$ (71,507)
Per share information:				
Net loss, basic and diluted	$ (0.29)	$ (0.41)	$ (1.43)	$ (1.51)
Weighted-average shares outstanding, basic and diluted	50,722,655	47,341,271	48,593,435	46,963,430

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Source: Chimerix, Inc.