

Chimerix Announces Fourth Quarter and Full Year 2017 Financial Results

March 1, 2018

- AdVance Data to be Presented at EBMT Annual Meeting -
 - Oral and IV BCV Programs Remain on Track -
 - Conference Call at 8:30 a.m. ET Today -

DURHAM, N.C., March 01, 2018 (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, 2017.

"We are pleased to announce that we have initiated AdAPT in both the US and EU, a study designed to provide comparative data on brincidofovir in patients with life-threatening adenovirus infection. As potentially the first treatment for adenovirus, oral brincidofovir could allow us to establish initial revenues as the IV brincidofovir program progresses," said M. Michelle Berrey, MD, MPH, President and Chief Executive Officer of Chimerix.

"Beyond brincidofovir, we are pleased with the progress of our ongoing first-time-in-human study for CMX521. As a proprietary nucleoside analog identified from our chemical library, CMX521 is the first antiviral specific for norovirus, a serious infection for which there is no currently approved treatment."

Program Updates

AdAPT: Short-Course Oral Brincidofovir for AdV Infection in Pediatric HCT Recipients

This study is targeting enrollment of 141 pediatric allogeneic hematopoietic cell transplant (HCT) recipients with confirmed clinically significant adenovirus (AdV) infection. Patients are randomized 2:1 to receive short-course oral brincidofovir (BCV) or the local standard-of-care (SOC) at approximately 30 sites across Europe and the United States.

The primary endpoint of the study is the average AdV viral burden (as measured by AdV levels in blood) over 16 weeks in subjects treated with short-course oral BCV versus those who receive local SOC. The study is 90% powered to show the superiority of reduced AdV viral burden in BCV-treated patients compared to SOC. The study will also evaluate the correlation of AdV viral burden (and its clearance) with clinical outcomes, including survival. Enrollment is estimated to complete in 2019.

Later this month, at the annual meeting of the European Society of Bone and Marrow Transplantation (EBMT), the Company will present final data on AdVance, a study of the incidence of AdV infection in HCT recipients and outcomes associated with the current SOC across Europe. Data from AdVance are expected to highlight the current gaps in treatment with SOC and the need for new therapeutic options.

Short-Course Oral BCV for Smallpox

Based on advice from the European Medicines Agency (EMA), the Company is preparing a Marketing Authorization Application (MAA) for submission to EMA in 2019. Chimerix also plans to submit a New Drug Application (NDA) for smallpox contingent upon the results of animal efficacy studies planned for 2018, including an adjunct study in the rabbitpox model.

IV Brincidofovir

Chimerix has successfully completed a multiple ascending dose (MAD) study of IV BCV in healthy subjects and is initiating Phase 2 studies in adult HCT recipients with AdV infection with data expected in the second half of 2018. The MAD study evaluated the safety, tolerability and pharmacokinetics of IV BCV 10 mg twice weekly and IV BCV 20 mg once weekly in healthy subjects for two to four weeks. IV BCV was well-tolerated at all dose levels, with no dose-limiting clinical adverse events. Importantly, there was no diarrhea reported for IV BCV 10 mg twice weekly, a dose that provides drug levels in plasma equivalent to oral BCV 100 mg, which demonstrated antiviral activity in previous late-stage clinical studies. Non-clinically-relevant elevations in serum transaminases were noted as seen in previous studies of oral BCV.

CMX521 for Norovirus Now in Phase 1

In late 2017, Chimerix initiated a first-time-in-human study of CMX521, a nucleoside analog from the Chimerix Chemical Library. CMX521 is the first antiviral specific for the treatment and/or prevention for norovirus. The Phase 1 study is evaluating the pharmacokinetics, safety and tolerability of CMX521 in up to 50 healthy adult subjects. The study also includes the collection of gut biopsy specimens, which will allow determination of active drug concentrations in the target gut tissue. Study results are expected in mid-2018.

Fourth Quarter 2017 Financial Results

Chimerix reported a net loss of \$19.2 million, or \$0.41 per basic and diluted share, for the fourth quarter of 2017. During the same period in 2016, Chimerix recorded a net loss of \$15.0 million, or \$0.32 per basic and diluted share.

Revenues for the fourth quarter of 2017 decreased to \$1.8 million, compared to \$2.0 million for the same period in 2016.

Research and development expenses were \$12.9 million for the three month period ended December 31, 2017, and \$11.7 million for the same period in 2016.

General and administrative expenses increased to \$7.6 million for the fourth quarter of 2017, compared to \$5.6 million for the same period in 2016.

Loss from operations was \$18.7 million for the fourth quarter of 2017, compared to a loss from operations of \$15.4 million for the same period in 2016.

Chimerix's balance sheet at December 31, 2017 included \$227.9 million of capital available to fund operations, no debt, and approximately 47.5 million outstanding shares of common stock.

Full Year 2017 Financial Results

Chimerix reported a net loss of \$71.0 million, or \$1.51 per basic and diluted share, for the year ended December 31, 2017. For the year ended December 31, 2016, Chimerix recorded a net loss of \$76.4 million, or \$1.65 per basic and diluted share.

Revenues for 2017 decreased to \$4.5 million, compared to \$5.7 million in 2016.

Research and development expenses were \$49.4 million for the year ended December 31, 2017, compared to \$58.6 million for the year ended December 31, 2016.

General and administrative expenses increased to \$27.1 million for the year ended December 31, 2017, compared to \$25.0 million for the year ended December 31, 2016.

Loss from operations was \$72.1 million for the year ended December 31, 2017, compared to a loss from operations of \$78.0 million for the year ended December 31, 2016.

Net interest income was \$2.3 million for the year ended December 31, 2017, compared to net interest income of \$1.6 million for the year ended December 31, 2016.

Today's Conference Call and Webcast

Chimerix will host a conference call and live audio webcast to discuss fourth quarter and full year 2017 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 1153769.

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 for adenovirus, cytomegalovirus (CMV) and smallpox. Brincidofovir has also received Orphan Medicinal Product Designation from the European Commission for adenovirus, CMV, and smallpox.

About Chimerix

Chimerix is a biopharmaceutical company dedicated to discovering, developing and commercializing medicines that improve outcomes for immunocompromised patients. Chimerix's proprietary lipid conjugate technology and Compound Library have produced brincidofovir (BCV, CMX001); CMX157, which was licensed to ContraVir Pharmaceuticals; and a new clinical candidate, CMX521, the first direct-acting antiviral specifically for the treatment and prevention of norovirus to enter clinical testing. 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 that there may not be a viable continued development path for brincidofovir, 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, 2017		December 31, 2016		
ASSETS						
Current assets:	•	10 5 10	•	E4 400		
Cash and cash equivalents	\$	-,	\$	51,463		
Short-term investments, available-for-sale		132,972		180,558		
Accounts receivable		1,682		1,599		
Prepaid expenses and other current assets		3,331		2,845		
Total current assets		156,533		236,465		
Long-term investments		76,731		47,407		
Property and equipment, net of accumulated depreciation		1,894		2,843		
Other long-term assets		72		55		
Total assets	\$	235,230	\$	286,770		
LIABILITIES AND STOCKHOLDERS' EQUITY						
Current liabilities:						
Accounts payable	\$	3,812	\$	3,890		
Accrued liabilities		9,384		6,215		
Total current liabilities		13,196		10,105		
Lease-related obligations		224		441		
Total liabilities		13,420		10,546		
Stockholders' equity:						
Preferred stock, \$0.001 par value, 10,000,000 shares authorized at December 31, 2017 and						
2016; no shares issued and outstanding as of December 31, 2017 and 2016		_		_		
Common stock, \$0.001 par value, 200,000,000 shares authorized at December 31, 2017 and						
2016; 47,505,532 and 46,522,475 shares issued and outstanding at						
December 31, 2017 and 2016, respectively		47		46		
Additional paid-in capital		709,514		692,422		
Accumulated other comprehensive loss, net		(963)	(440)	
Accumulated deficit		(486,788)	(415,804)	
Total stockholders' equity		221,810	•	276,224	•	
Total liabilities and stockholders' equity	\$	235,230	\$	286,770		

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,					
	2017	2016	2017	2016				
Contract revenue	\$ 1,844	\$ 1,980	\$ 4,49	4 \$ 5,702				
Operating expenses:								
Research and development	12,913	11,705	49,4	48 58,647				
General and administrative	7,618	5,648	27,1	48 25,007				
Total operating expenses	20,531	17,353	76,5	96 83,654				
Loss from operations	(18,687) (15,373) (72,1	102) (77,952)			
Other (expense) income:								
Other-than-temporary impairment of investment	(1,160) -	(1,16	60) -				
Interest income	609	416	2,27	8 1,562				
Net loss	(19,238) (14,957) (70,9	984) (76,390)			

Other comprehensive loss:

Unrealized gain (loss) on investments, net	518		(74)	(523)	324	
Comprehensive loss	\$ (18,720)	\$ (15,031)	\$ (71,507) \$	(76,066)
Per share information:								
Net loss, basic and diluted	\$ (0.41)	\$ (0.32)	\$ (1.51) \$	(1.65)
Weighted-average shares outstanding, basic and diluted	47,341,271		46,431,809		46,963,430		46,267,064	



Source: Chimerix, Inc.