Chimerix Announces Third Quarter 2018 Financial Results

November 8, 2018

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

DURHAM, N.C., Nov. 08, 2018 (GLOBE NEWSWIRE) -- Chimerix (NASDAQ:CMRX), a biopharmaceutical company developing novel antivirals to address life-threatening viral infections, today reported financial results and provided a corporate update for the third quarter ended September 30, 2018.

"We have made important progress throughout the year that we believe will position Chimerix for several transformational catalysts in 2019. We expect AdAPT to fully enroll in 2019 and provide data in 2020. Data from our Phase 2 studies of IV BCV should inform the design and doses of BCV in other viral infections such as BK virus and HHV-6. Results from our pivotal animal studies supporting BCV for smallpox are anticipated in 2019. Finally, our financial position remains strong, providing the capital needed to advance our clinical programs for BCV and CMX521," said M. Michelle Berrey, MD, MPH, President and Chief Executive Officer of Chimerix.

Recent Highlights and Program Updates:

Detailed AdVance Data Presented at IDWeek

At IDWeek 2018 in early October, Chimerix presented the full analysis of multiple measures of adenovirus (AdV) viral load dynamics from the AdVance study. AdVance was the first large, multi-center study of AdV incidence, natural history, management and clinical outcomes in allogeneic hematopoietic cell transplant (allo-HCT) recipients.

The analysis considered **six different dynamic measures of AdV viral load and their association with all-cause mortality. Importantly,** all measures were independently associated with mortality, including the viral burden measured as time-averaged area-under-the-curve for AdV viral load over 16 weeks ($AAUC_{0-16}$). As with many viral infections, peak viral load and the duration of the high viral load were both predictors of poor clinical outcomes. The area-under-the-curve includes both measures: viral peak and persistence. As the primary endpoint in the ongoing AdAPT study, the company believes AdV $AAUC_{0-16}$ is thus likely to reflect the superior antiviral effect of oral brincidofovir (BCV) compared with current standard of care and may also demonstrate the improved short-term outcomes in subjects who are treated with oral BCV.

Data from Multiple Ascending Dose Study of IV Brincidofovir Presented at IDWeek

Chimerix presented data from the company's Phase 1 study evaluating the safety and pharmacokinetics (PK) of multiple ascending doses (MAD) of intravenous (IV) BCV in healthy adult subjects. These data were presented at IDWeek 2018.

The study evaluated the safety and PK of four doses of IV BCV in 27 healthy individuals who were randomized 3:1 to receive IV BCV or placebo in sequential cohorts of escalating doses. Individuals receiving IV BCV were given a 10 mg dose in a two-hour infusion twice a week for two weeks or a 20 mg dose in either a one- or two-hour infusion once a week for four weeks. Twice weekly doses of IV BCV at 10 mg provided similar blood levels of the drug as the oral BCV 100 mg dose previously studied in late-stage clinical trials, with no reported diarrhea or other gastrointestinal adverse events.

Preclinical Data Demonstrating Antiviral Activity of BCV Against Polyomavirus Presented at Kidney Week 2018

Chimerix announced data from two preclinical studies which assessed the in vivo antiviral activity of BCV against polyomavirus. These data were presented at the American Society of Nephrology's Kidney Week 2018 in San Diego, CA.

The two studies evaluated BCV's effect against Murine Polyoma Virus (MuPyV), a mouse polyomavirus closely related to the human BK virus. In these studies, mice with MuPyV were treated with BCV either 24 hours after being infected or prophylactically for a full week prior to infection. Data from the two studies show that BCV demonstrated significant antiviral activity against MuPyV and showed no safety signals across BCV doses administered. In mice treated after infection with MuPyV, BCV delivered via intraperitoneal injection once daily, twice weekly or once weekly reduced kidney viral loads by 100-fold relative to placebo. These data along with data from the company's ongoing Phase 2 studies of IV BCV are expected to inform the dose regimen for the company's planned Phase 2/3 studies.

Program Updates

Oral BCV

The AdAPT Study (Adenovirus after Allogeneic Pediatric Transplantation) is open for enrollment in the United States (US) and Europe. All targeted countries and clinical sites are anticipated to be open for enrollment by the end of 2018. Chimerix anticipates completing enrollment in 2019 and obtaining results from the 16-week primary endpoint in 2020; however, this forecast will likely be updated once the company has several months of data on the enrollment rate from a majority of planned clinical centers.

IV BCV Phase 2 Studies Continue to Initiate in the US and Europe

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. The company anticipates interim data in 2019. Building on the recently-presented data from IV BCV in healthy adults, the safety and BCV levels in patients, together

with AdV viral decay curves, will inform the design of future Phase 2/3 studies.

Final Animal Studies for Brincidofovir for the Treatment of Smallpox

Chimerix recently initiated the adjunct rabbit study and anticipates initiating the pivotal mouse efficacy study in 2019. Data from both animal efficacy models are expected in 2019. Chimerix intends to submit marketing applications for oral BCV for smallpox following the completion of the rabbit and mouse efficacy studies.

CMX521 for Norovirus

In September 2018, Chimerix presented data on CMX521 at the European Society for Clinical Virology in Athens, Greece. The data presented included:

- No safety concerns were identified with single oral doses of CMX521 up to 2400 mg the top dose tested
- CMX521 plasma exposures increased in a less-than-proportional manner with escalating single oral dose administration

Clinical testing of CMX521 is ongoing in conjunction with in vitro studies in cultured human intestinal cells and recently described animal models of norovirus to assess antiviral efficacy.

Third Quarter 2018 Financial Results

Chimerix reported a net loss of $16.1 million, or $0.33 per basic and diluted share, for the third quarter of 2018. During the same period in 2017, Chimerix recorded a net loss of $17.3 million, or $0.37 per basic and diluted share.

Revenues for the third quarter of 2018 decreased to $0.4 million, compared to $0.9 million for the same period in 2017.

Research and development expenses decreased to $11.9 million for the third quarter of 2018, compared to $12.2 million for the same period in 2017.

General and administrative expenses decreased to $5.2 million for the third quarter of 2018, compared to $6.7 million for the same period in 2017.

Loss from operations was $16.7 million for the third quarter of 2018, compared to a loss from operations of $17.9 million for the same period in 2017.

Chimerix's balance sheet at September 30, 2018 included $193.8 million of capital available to fund operations, no debt, and approximately 50.6 million outstanding shares of common stock.

Today's Conference Call and Webcast

Chimerix will host a conference call and live audio webcast to discuss third quarter 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 4646308.

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 cytomegalovirus (CMV) and smallpox. Brincidofovir has also received Orphan Medicinal Product Designation from the European Commission for the treatment of adenovirus, for the prevention of CMV disease, and for the treatment of smallpox, and Orphan Drug Designation from the FDA for the treatment of smallpox.

About CMX521

CMX521 is a nucleoside antiviral identified from the Chimerix Chemical Library as a potential treatment and/or prevention for norovirus, the most common cause of acute gastroenteritis worldwide. An ongoing Phase 1 study is evaluating the pharmacokinetics, safety and tolerability of CMX521.

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 CMX521, the first clinical-stage direct-acting antiviral for the treatment and/or prevention of norovirus. 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 the 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 Quarterly Report on Form 10-Q 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)
(unaudited)

	September 30, 2018	December 31, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	$ 22,991	$ 18,548
Short-term investments, available-for-sale	160,367	132,972
Accounts receivable	332	1,682
Prepaid expenses and other current assets	3,028	3,331
Total current assets	186,718	156,533
Long-term investments	10,564	76,731
Property and equipment, net of accumulated depreciation	1,363	1,894
Other long-term assets	51	72
Total assets	$ 198,696	$ 235,230
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,609	$ 3,812
Accrued liabilities	7,776	9,384
Total current liabilities	9,385	13,196
Lease-related obligations	167	224
Total liabilities	9,552	13,420
Stockholders' equity:		
Preferred stock, $0.001 par value, 10,000,000 shares authorized at September 30, 2018 and December 31, 2017; no shares issued and outstanding as of September 30, 2018 and December 31, 2017	—	—
Common stock, $0.001 par value, 200,000,000 shares authorized at September 30, 2018 and December 31, 2017; 50,627,237 and 47,505,532 shares issued and outstanding as of September 30, 2018 and December 31, 2017, respectively	51	47
Additional paid-in capital	731,060	709,514
Accumulated other comprehensive loss, net	(661)	(963)
Accumulated deficit	(541,306)	(486,788)
Total stockholders' equity	189,144	221,810
Total liabilities and stockholders' equity	$ 198,696	$ 235,230

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,	
	2018	**2017**	**2018**	**2017**
Contract revenue	$ 369	$ 897	$ 2,352	$ 2,650
Operating expenses:				
Research and development	11,892	12,157	39,963	36,535
General and administrative	5,187	6,650	18,575	19,530
Total operating expenses	17,079	18,807	58,538	56,065
Loss from operations	(16,710)	(17,910)	(56,186)	(53,415)
Other (expense) income:				
Unrealized loss on equity investment	(99)	-	(311)	-
Interest income	730	598	1,979	1,669
Net loss	(16,079)	(17,312)	(54,518)	(51,746)
Other comprehensive loss:				
Unrealized gain (loss) on investments, net	180	(6)	302	(1,041)
Comprehensive loss	$ (15,899)	$ (17,318)	$ (54,216)	$ (52,787)
Per share information:				
Net loss, basic and diluted	$ (0.33)	$ (0.37)	$ (1.14)	$ (1.10)
Weighted-average shares outstanding, basic and diluted	48,172,354	47,065,756	47,875,895	46,836,099

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Source: Chimerix, Inc.