

Chimerix Announces Fourth Quarter and Full Year 2013 Financial Results

Brincidofovir (CMX001) Progressing in Phase 3 SUPPRESS Trial for Prevention of Cytomegalovirus Infection

DURHAM, N.C., March 7, 2014 (GLOBE NEWSWIRE) -- Chimerix, Inc. (Nasdaq:CMRX), a biopharmaceutical company developing novel, oral antivirals in areas of high unmet medical need, today reported financial results for the fourth quarter and full year 2013.

Update on Phase 3 SUPPRESS Trial of Brincidofovir (CMX001)

Enrollment of the planned 450 total subjects in Chimerix's Phase 3 SUPPRESS trial of brincidofovir is on track to deliver pivotal data in mid-2015. Positive results from SUPPRESS would be used to support Accelerated Approval of brincidofovir for the prevention of cytomegalovirus (CMV), the first approval of an antiviral for the prevention of CMV in recipients of hematopoietic cell transplants (HCT), also known as bone marrow transplantation. SUPPRESS's secondary endpoints include clinical events related to other DNA viruses common in HCT recipients, including adenovirus (AdV), BK virus (BKV), HHV-6, and Epstein-Barr virus. Additional endpoints will evaluate bacterial and other opportunistic infections, mortality and measurements of healthcare utilization.

"We are enthusiastic about brincidofovir's potential to prevent clinically significant viral infections in bone marrow transplant recipients, and look forward to expanding the compound's development activities to other DNA viruses and other patient populations," said Kenneth I. Moch, President and CEO of Chimerix. "With the recent hiring of Linda Richardson as our Chief Commercial Officer, we are working to prepare our pre-launch strategies and to establish our commercial infrastructure."

"In 2014, we plan to present and publish existing data demonstrating brincidofovir's activity in a broad spectrum of viruses and populations. Our recent oral presentations at the BMT Tandem Meeting reviewed the safety and tolerability of brincidofovir in highly immunocompromised pediatric patients and the antiviral activity of brincidofovir in adults and children with AdV infection, an often fatal infection with no available therapy," said M. Michelle Berrey, MD, MPH, Chief Medical Officer of Chimerix.

Fourth Quarter 2013 Financial Results

Chimerix reported a net loss of \$8.2 million, or \$0.31 per basic and diluted share, for the fourth quarter of 2013. During the same period in 2012, Chimerix recorded a net loss of \$4.3 million, or \$3.90 per basic and diluted share.

Revenues for the fourth quarter of 2013 decreased to \$879,000, compared to \$3.6 million for the same period in 2012, due to a decrease in the fourth quarter of 2013 in reimbursable expenses associated with Chimerix's ongoing contract with the Biomedical Advanced Research and Development Authority (BARDA).

Research and development expenses were \$6.3 million for the fourth quarter of 2013, and \$6.3 million for the same period in 2012. General and administrative expenses increased to \$2.6 million for the fourth quarter of 2013, compared to \$1.4 million for the same period in 2012. The increase primarily relates to costs associated with the growth of the business and operating as a publicly-traded company.

Loss from operations was \$8.0 million for the fourth quarter of 2013, compared to a loss from operations of \$4.1 million for the same period in 2012. The variance is due primarily to the decrease in revenue related to the BARDA contract along with the increase in general and administrative expenses.

Interest expense was \$195,000 in the fourth quarter of 2013, compared to \$409,000 in the same period in 2012. The decrease is based upon a decline in the outstanding loan payable principal balance in 2013 as a result of payments made following the draw-down of \$12.0 million in the third quarter of 2012.

For the fourth quarter of 2013, there were no fair value of warrant charges as all of the outstanding preferred warrants converted to common stock warrants upon the completion of the IPO in April 2013. For the fourth quarter of 2012, the company recorded other income of \$226,000 due to the change in company valuation.

Chimerix's balance sheet at December 31, 2013 included \$110.0 million in cash and cash equivalents, \$9.9 million in debt and approximately 26.7 million outstanding shares of common stock.

Full Year 2013 Financial Results

Chimerix reported a net loss of \$36.4 million, or \$3.65 per basic and diluted share, for the year ended December 31, 2013. For the year ended December 31, 2012, the Company recorded net loss of \$4.4 million, or \$5.75 per basic and diluted share.

Revenues for 2013 decreased to \$4.4 million, compared to \$33.7 million in 2012, due to a decrease in 2013 in reimbursable expenses associated with Chimerix's ongoing contract with BARDA and the receipt of an upfront license payment related to Chimerix's collaboration and license arrangement with Merck in 2012.

Research and development expenses were \$24.7 million for the year ended December 31, 2013, compared to \$30.1 million for the year ended December 31, 2012. The decrease is due primarily to a decrease in clinical trial expenses related to the completion of multiple Phase 1 and Phase 2 clinical studies in 2012. General and administrative expenses increased to \$8.3 million for the year ended December 31, 2013, compared to \$6.4 million for the year ended December 31, 2012. The increase primarily relates to costs associated with the growth of the business and operating as a publicly-traded company.

Loss from operations was \$28.6 million for the year ended December 31, 2013, compared to a loss from operations of \$2.8 million for the year ended December 31, 2012. The variance is due primarily to the decrease in revenue related to the BARDA contract and the receipt of the Merck upfront license payment during 2012.

Interest expense was \$1.2 million for the year ended December 31, 2013, compared to \$776,000 for the year ended December 31, 2012. The increase was due to a full year of expense related to the \$12.0 million second tranche of the outstanding loan payable drawn in the third quarter of 2012.

The fair value adjustment to the warrant liability increased to \$6.6 million for the year ended December 31, 2013, compared to \$847,000 for the year ended December 31, 2012, due to an increase of non-cash expense related to the periodic revaluation of Chimerix's warrant liability. This increase was attributable to the significant increase in the fair value of Chimerix stock prior to the IPO in April 2013.

Today's Conference Call and Webcast

Chimerix will host a conference call and live audio webcast to discuss its fourth quarter and full year 2013 accomplishments and financial results 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 3880607.

A live audio webcast of the call will also be available on the Investors section of Chimerix's website, <u>www.chimerix.com</u>. An archived webcast will be available on the Chimerix website approximately two hours after the event.

About Brincidofovir (CMX001)

Chimerix's lead product candidate, brincidofovir, has the potential to be the first broad-spectrum antiviral for the prevention and treatment of clinically significant infections and diseases caused by DNA viruses. Brincidofovir is an oral nucleotide analog that has shown broad-spectrum antiviral activity against all five families of DNA viruses that affect humans, including CMV, AdV, BKV and herpes simplex viruses. Brincidofovir has shown a favorable safety and tolerability profile, with no evidence of kidney or bone marrow toxicity in nearly 900 patients dosed with brincidofovir to date. In September 2013, data from Chimerix's Phase 2 trial of brincidofovir in the prevention of CMV in recipients of HCT were published in the *New England Journal of Medicine* (N Engl J Med 369:1227-36).

Building on the positive Phase 2 results in CMV, Chimerix initiated the Phase 3 SUPPRESS trial in the third quarter of 2013 which, if positive, will be used to support Chimerix's initial regulatory submission for prevention of CMV infection in adult HCT recipients. Chimerix recently presented results from its Phase 2 trial in AdV, an often-fatal infection with no approved treatment. A brincidofovir dose of 100 mg twice weekly, the dose being used in SUPPRESS, demonstrated a potent antiviral effect on levels of AdV in the blood, and a numeric decrease in overall mortality. Chimerix is also working with BARDA to develop brincidofovir as a medical countermeasure against smallpox.

About the Phase 3 SUPPRESS Trial

SUPPRESS is designed to demonstrate the efficacy and safety of brincidofovir for the prevention of CMV infection versus a placebo control, as no therapy is currently approved for the prevention of CMV in HCT recipients. The primary endpoint for SUPPRESS is the rate of clinically significant CMV infection through the first 24 weeks post-transplant. The trial is powered to

detect a relative 50% decrease in clinically significant CMV infection in subjects receiving brincidofovir versus those receiving placebo. Secondary endpoints in the SUPPRESS trial include clinical and virologic evidence of DNA viral infections, including AdV, BKV and other herpes viruses such as HHV-6 and varicella zoster virus that contribute to morbidity and mortality in the first year following HCT.

SUPPRESS is anticipated to enroll approximately 450 HCT recipients who are at increased risk of CMV infection, with approximately 300 subjects receiving 100 mg twice weekly brincidofovir and 150 receiving placebo (2-to-1 ratio). Approximately 40 transplant centers will participate in SUPPRESS. Initiation of dosing will not require evidence of stem cell "engraftment" (evidence of production of blood cells by the new transplant), a safety precaution incorporated into previous into previous trials of investigational antivirals for CMV prevention, and therefore dosing in SUPPRESS can begin as soon after transplant as a subject can swallow oral medication. Enrolled subjects will receive brincidofovir or placebo through Week 14 post-transplant, the period of highest risk for viral reactivation, and will continue to be monitored for evidence of CMV and other DNA viral infections through Week 24 post-transplant.

Data from SUPPRESS are anticipated in mid-2015 and, if positive, would be used to support Accelerated Approval of brincidofovir for the prevention of CMV infection.

About Cytomegalovirus (CMV)

CMV is a member of the herpes virus family and is the most common infectious pathogen in transplant recipients. Two-thirds of adults in the United States have been exposed to CMV, generally in childhood, with lifelong viral latency established following the initial infection. In healthy individuals, a functioning immune system protects an infected individual against future exposure to CMV but does not clear the virus from their body. In immunocompromised individuals such as transplant recipients, CMV often reactivates during the post-transplant period when the immune system is weak and rebuilding itself. CMV infection is known to correlate with progression to CMV disease and death. CMV itself is immunosuppressive and reactivation of the virus can predispose a patient to other opportunistic viral infections in addition to fungal and bacterial infections. No therapies are approved for the prevention of CMV in HCT recipients. While currently available systemic anti-CMV agents can be effective against CMV, their use is limited by significant toxicities, including bone marrow suppression and renal impairment, and these therapies are only approved for certain solid organ transplant patient populations.

About Chimerix

Chimerix is a biopharmaceutical company dedicated to developing and commercializing novel, oral antivirals in areas of high unmet medical need. Chimerix's proprietary technology has given rise to two clinical-stage nucleotide analog lipid-conjugates, brincidofovir and CMX157, both of which have demonstrated the potential for enhanced activity and safety in convenient, orally administered dosing regimens. In the third quarter of 2013, Chimerix initiated the Phase 3 SUPPRESS trial of brincidofovir for the prevention of CMV infection in adult HCT recipients, also known as bone marrow transplants. Brincidofovir has shown broad-spectrum activity against all five families of DNA viruses that affect humans, including CMV, AdV, BKV and herpes simplex viruses. Brincidofovir has received Fast Track designation by the FDA, and the Phase 3 data, if positive, would be used to support Accelerated Approval of brincidofovir for the prevention of CMV infection in adult HCT recipients are medical countermeasure against smallpox. Chimerix's second product candidate, CMX157, was licensed to Merck in July 2012 for the treatment of HIV infections. For further information, please visit Chimerix's website, www.chimerix.com.

Forward-Looking Statements

Statements contained in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Risks are described more fully in Chimerix's filings with the Securities and Exchange Commission, including without limitation its most recent Annual Report on Form 10-K, its most recently filed Current Reports on Form 8-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. Chimerix undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

CHIMERIX, INC. BALANCE SHEETS (in thousands) (unaudited)

Current assets:		
Cash and cash equivalents	\$ 109,976	\$ 19,906
Short-term investments, available-for-sale		9,849
Accounts receivable	248	783
Prepaid and other current assets	2,765	983
Deferred financing costs, current portion	20	33
Total current assets	113,009	31,554
Property and equipment, net of accumulated depreciation	338	407
Deposits and prepaid assets, less current portion	30	22
Deferred financing costs, less current portion	10	48
Total assets	\$ 113,387	\$ 32,031
Liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)		
Current liabilities:	* • • • • • •	.
Accounts payable	\$ 2,214	\$ 1,964
Accrued liabilities	2,420	906
Loan payable, current portion	5,573	4,753
Total current liabilities	10,207	7,623
Other long-term liabilities	347	337
Loan payable, less current portion	4,294	9,867
Redeemable convertible preferred stock warrant liability		7,512
Total liabilities	14,848	25,339
Redeemable convertible preferred stock		107,723
Stockholders' equity (deficit):		
Common stock	26	3
Additional paid-in capital	261,243	
Accumulated other comprehensive loss		(2)
Accumulated deficit	(162,730)	(101,032)
Total stockholders' equity (deficit)	98,539	(101,031)
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	\$ 113,387	\$ 32,031

CHIMERIX, INC.

STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(in thousands, except share and per share data)

(unaudited)

	Three Months Ended December 31,		Year Ended December 31,	
	2013	2012	2013	2012
Revenues:				
Contract revenue	\$ 879	\$ 3,581	\$ 4,370	\$ 16,275
Collaboration and licensing revenue				17,445
Total revenues	879	3,581	4,370	33,720

Operating expenses:

Research and development	6,284	6,283	24,662	30,106
General and administrative	2,574	1,441	8,327	6,397
Loss from operations	(7,979)	(4,143)	(28,619)	(2,783)
Other expense:				
Other expense, net	(195)	(409)	(1,236)	(776)
Fair value adjustments to warrant liability		226	(6,590)	(847)
Net loss	(8,174)	(4,326)	(36,445)	(4,406)
Other comprehensive loss:				
Unrealized (loss) gain on securities available-for-sale	(1)	(2)	2	2
	\$ (8,175)	\$ (4,328)	\$ (36,443)	\$ (4,404)
Comprehensive loss	φ(0,170)	φ (4,320)	φ (30,443)	ψ (+,+0+)
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Net loss per common share, basic & diluted	\$ (0.31)	\$ (3.90)	\$ (3.65)	\$ (5.75)
Weighted-average shares outstanding, basic & diluted	26,416,787	1,532,633	19,307,422	1,524,628

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