



**CHIMERIX**

November 14, 2013

## **Chimerix Announces Third Quarter 2013 Financial Results**

### **Initiated Phase 3 SUPPRESS Trial of Brincidofovir (CMX001) for Prevention of Cytomegalovirus Infection in Hematopoietic Cell Transplant Recipients in Third Quarter 2013**

DURHAM, N.C., Nov. 14, 2013 (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 quarter ended September 30, 2013.

#### **Business Highlights**

##### -- Brincidofovir for the Prevention of Cytomegalovirus (CMV) Infection

- Chimerix initiated the Phase 3 SUPPRESS trial of brincidofovir for the prevention of CMV in recipients of hematopoietic cell transplants (HCT), also known as bone marrow transplants. CMV, a double-stranded DNA (dsDNA) virus, causes life-threatening infections in patients whose immune systems are compromised after receiving a transplant or other therapies. Enrollment of the planned 450 subjects is on track to deliver pivotal data in mid-2015. Positive results from SUPPRESS would be supportive of Accelerated Approval of brincidofovir for the prevention of CMV, the first approval of an antiviral for the prevention of CMV in HCT recipients.
- Results from Study 201, a Phase 2 study that evaluated brincidofovir for the prevention of CMV in 230 HCT recipients, were published in the September 26, 2013 issue of the *New England Journal of Medicine*. This publication highlights the importance of brincidofovir and its potential to change the standard of care in this area of high unmet medical need.

##### -- Brincidofovir as Preemptive Therapy for Adenovirus (AdV)

- Data from Study 202, a Phase 2 study of brincidofovir as a preemptive therapy for AdV infection, were presented during an oral, late-breaker session at the Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC) in September 2013. The results showed potential clinical benefit in reducing progression to AdV disease and all-cause mortality. The rates of adverse events leading to discontinuation were the same between the brincidofovir and placebo cohorts, and there were no new safety findings for brincidofovir.
- The Company is in discussions with key opinion leaders and the U.S. Food and Drug Administration (FDA) regarding next steps for the AdV program and brincidofovir's overall pediatric program.

##### -- Issuance of Additional Composition of Matter Patent Covering Brincidofovir

- The United States Patent and Trademark Office issued U.S. Patent No. 8,569,321 to Chimerix covering a method of synthesis and a morphic form of brincidofovir. With the addition of this most recent patent, composition of matter coverage for brincidofovir in the U.S. is expected to extend to August 2031.

##### -- Secondary Public Offering of Common Stock

- Chimerix completed a secondary public offering of 2,476,995 shares of common stock held by certain existing stockholders on October 23, 2013. Chimerix did not issue any shares of common stock and received no proceeds in connection with this offering. The principal purposes of the offering were to facilitate an orderly distribution of shares and increase the Company's public float.

"During the third quarter, Chimerix achieved one of the most important milestones in the Company's history by initiating the Phase 3 SUPPRESS trial of brincidofovir. Brincidofovir has the potential to change the standard of care in this area of high unmet medical need," said Kenneth I. Moch, President and CEO of Chimerix.

"The rate of non-relapse mortality is approximately 20% in the first year following HCT, caused by post-transplant complications, including viral, bacterial and fungal infections and graft failure. Based on the positive Phase 2 study results of brincidofovir and the study design for SUPPRESS, we are optimistic about the likelihood of positive results from the trial and the potential for brincidofovir to bring meaningful benefit to patients," said M. Michelle Berrey, MD, MPH, Chief Medical Officer of

Chimerix.

### **Third Quarter 2013 Financial Results**

Chimerix reported a net loss of \$6.7 million, or \$0.26 per basic and diluted share for the third quarter of 2013. During the same period in 2012, the Company recorded net income of \$11.1 million, or \$6.70 per basic share and \$0.11 per diluted share. The third quarter of 2012 was profitable on a stand-alone basis and therefore included both basic and diluted net income per share. This was due to the one-time payment from Merck, Sharp & Dohme Corp. (Merck) discussed below.

Revenues for the third quarter of 2013 decreased to \$912,000, compared to \$20.9 million for the same period in 2012, due to a combination of a one-time upfront license payment of \$17.5 million related to the exclusive license of CMX157 to Merck in the third quarter of 2012, as well as a decrease in the third quarter of 2013 in reimbursable expenses associated with the Company's ongoing contract with the Biomedical Advanced Research and Development Authority (BARDA).

Research and development expenses decreased to \$5.3 million for the third quarter of 2013, compared to \$7.7 million for the same period in 2012. The variance is related to decreased clinical trial and manufacturing expenses during the third quarter of 2013 as compared to the same period in 2012, as well as license fees associated with CMX157 during the third quarter of 2012.

General and administrative expenses increased to \$2.0 million for the third quarter of 2013, compared to \$1.8 million for the same period in 2012. The increase relates to costs associated with operating as a publicly traded company, including legal fees, accounting fees and non-employee director compensation.

Loss from operations was \$6.4 million for the third quarter of 2013, compared to an income from operations of \$11.3 million for the same period in 2012. The significant variance is attributable to the one-time upfront license payment of \$17.5 million related to the exclusive license of CMX157 to Merck in July 2012.

Interest expense was \$270,000 in the third quarter of 2013, compared to \$130,000 in the same period in 2012, based on the larger outstanding loan balance following a draw-down of \$12.0 million of venture debt late in the third quarter of 2012.

Chimerix's balance sheet at September 30, 2013 included \$116.9 million in cash, cash equivalents and short-term investments, \$11.3 million in debt and 26.0 million outstanding shares of common stock.

### **Today's Conference Call and Webcast**

Chimerix will host a conference call and live audio webcast to discuss its third quarter 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 91867511.

A live audio webcast of the call will also be available on the Investors section of Chimerix's website, [www.chimerix.com](http://www.chimerix.com). 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 (CMX001), is an oral nucleotide analog that has shown broad-spectrum antiviral activity against all five families of dsDNA viruses that affect humans, including CMV, AdV, BK virus (BKV) and herpes simplex viruses. Brincidofovir has a favorable safety and tolerability profile, with no evidence of kidney or bone marrow toxicity in nearly 900 patients dosed with brincidofovir to date. Chimerix believes that brincidofovir has the potential to be the first broad-spectrum antiviral for the prevention and treatment of clinically significant infections and diseases caused by dsDNA viruses.

Following positive Phase 2 results, in the third quarter of 2013 Chimerix initiated the Phase 3 SUPPRESS trial which will 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 adenovirus, an often-fatal infection with no approved treatment. A brincidofovir dose of 100 mg twice weekly demonstrated a potent antiviral effect on levels of AdV in the blood, and a numeric decrease in overall mortality. Chimerix continues to work with the Biomedical Advanced Research and Development Authority (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 dsDNA viral infections, including AdV, BKV and other herpesviruses 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. Dosing of study drug will begin shortly after subjects receive their transplant, and will not require evidence of stem cell "engraftment" (evidence of production of blood cells by the new transplant), a safety precaution incorporated in the Phase 2 trial of brincidofovir and other recent trials of investigational antivirals for CMV prevention. Enrolled subjects will continue on brincidofovir or placebo through Week 14 post-transplant, the period of highest risk for viral reactivation. Subjects will continue to be monitored for evidence of CMV and other dsDNA viral infections through Week 24 post-transplant.

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

### ***About Cytomegalovirus (CMV) and Double-Stranded DNA (dsDNA) Viruses***

CMV is a member of the herpesvirus family and is the most common infectious pathogen in transplant recipients. A majority of adults in the US have been exposed to CMV, generally in childhood, with lifelong viral latency established following resolution. In healthy individuals with a functioning immune system, CMV remains dormant throughout life. 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 with weakened immune systems, such as transplant recipients, CMV often reactivates during the post-transplant period when the immune system is rebuilding itself. No therapies are approved for the prevention of CMV in HCT recipients. Currently available systemic anti-CMV agents can be effective against CMV; however, 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. 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.

### ***About Chimerix***

Chimerix is committed to the discovery, development and commercialization of novel, oral antiviral therapeutics designed to transform patient care in areas of high unmet medical need. Chimerix's proprietary lipid technology has given rise to two clinical-stage nucleotide analog lipid-conjugates, brincidofovir (CMX001) and CMX157, which have demonstrated the potential for enhanced activity and safety in convenient, orally administered dosing regimens. Chimerix's lead product candidate, brincidofovir, is an oral nucleotide analog that has shown broad-spectrum antiviral activity against all five families of dsDNA viruses that affect humans, including CMV, AdV, BKV and herpes simplex viruses. Chimerix's second product candidate, CMX157, an oral nucleotide analog for the treatment of HIV infection, was licensed to Merck in July 2012. For further information, please visit Chimerix's website, [www.chimerix.com](http://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. Such statements include, but are not limited to, statements regarding the likelihood of positive results from the SUPPRESS trial, the efficacy of brincidofovir and its ability to provide a broad spectrum of antiviral activity, and the positive impact of brincidofovir on transplant recipients. Risks that contribute to the uncertain nature of the forward-looking statements include: the success of the SUPPRESS trial; the demonstrated efficacy of brincidofovir in the SUPPRESS trial; Chimerix's financial position; and regulatory developments in the United States and foreign countries. Other risks and uncertainties affecting Chimerix are described more fully in Chimerix's filings with the Securities and Exchange Commission, including without limitation its most recently filed Quarterly Report on Form 10-Q and its most recently filed 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, except share and per share data)**

**(unaudited)**

	<u>September 30, 2013</u>	<u>December 31, 2012</u>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 115,891	\$ 19,906
Short-term investments, available-for-sale	1,004	9,849
Accounts receivable	190	783
Prepaid and other current assets	2,683	983
Deferred financing costs, current portion	<u>20</u>	<u>33</u>
Total current assets	119,788	31,554
Property and equipment, net of accumulated depreciation	335	407
Deposits	20	22
Deferred financing costs, less current portion	<u>15</u>	<u>48</u>
Total assets	<u>\$ 120,158</u>	<u>\$ 32,031</u>
<b>Liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)</b>		
Current liabilities:		
Accounts payable	\$ 1,770	\$ 1,964
Accrued liabilities	1,601	906
Loan payable, current portion	<u>5,597</u>	<u>4,753</u>
Total current liabilities	8,968	7,623
Other long-term liabilities	345	337
Loan payable, less current portion	5,715	9,867
Redeemable convertible preferred stock warrant liability	<u>--</u>	<u>7,512</u>
Total liabilities	15,028	25,339
Redeemable convertible preferred stock	--	107,723
Stockholders' equity (deficit):		
Common stock, \$0.001 par value, 200,000,000 and 89,700,000 shares authorized at September 30, 2013 and December 31, 2012, respectively; 25,974,809 and 1,533,996 shares issued and outstanding as of September 30, 2013 and December 31, 2012, respectively	26	3
Additional paid-in capital	259,661	--
Accumulated other comprehensive loss	--	(2)
Accumulated deficit	(154,557)	(101,032)
Total stockholders' equity (deficit)	<u>105,130</u>	<u>(101,031)</u>
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	<u>\$ 120,158</u>	<u>\$ 32,031</u>

**CHIMERIX, INC.**  
**STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS**  
(in thousands, except share and per share data)  
(unaudited)

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2013</u>	<u>2012</u>	<u>2013</u>	<u>2012</u>
Revenues:				
Contract revenue	\$ 912	\$ 3,411	\$ 3,491	\$ 12,694

Collaboration and licensing revenue	--	17,445	--	17,445
Total revenues	912	20,856	3,491	30,139
Operating expenses:				
Research and development	5,319	7,748	18,379	23,823
General and administrative	2,029	1,836	5,753	4,956
(Loss) income from operations	(6,436)	11,272	(20,641)	1,360
Other expense:				
Interest expense, net	(270)	(130)	(1,041)	(367)
Fair value adjustments to warrant liability	--	--	(6,590)	(1,073)
Net (loss) income	(6,706)	11,142	(28,272)	(80)
Other comprehensive gain (loss):				
Unrealized gain (loss) on securities available-for-sale	1	(3)	3	4
Comprehensive (loss) income	<u>\$ (6,705)</u>	<u>\$ 11,139</u>	<u>\$ (28,269)</u>	<u>\$ (76)</u>
Per share information:				
Net (loss) income per common share, basic	<u>\$ (0.26)</u>	<u>\$ 6.70</u>	<u>\$ 3.69</u>	<u>\$ (1.82)</u>
Weighted-average shares outstanding, basic	<u>25,866,109</u>	<u>1,529,442</u>	<u>16,911,592</u>	<u>1,524,489</u>
Net (loss) income per common share, diluted	<u>\$ (0.26)</u>	<u>\$ 0.11</u>	<u>\$ (3.69)</u>	<u>\$ (1.82)</u>
Weighted-average shares outstanding, diluted	<u>25,866,109</u>	<u>52,933,956</u>	<u>16,911,592</u>	<u>1,524,489</u>

**CHIMERIX, INC.**  
**STATEMENTS OF CASH FLOWS**  
(in thousands)  
(unaudited)

**Nine Months Ended September 30,**  
2013      2012

**Operating activities:**

Net loss	\$ (28,272)	\$ (80)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	197	210
Non-cash interest expense	46	175
Amortization/accretion of premium/discount on investments	416	29
Share-based compensation costs	2,853	1,133
Fair value measurement of redeemable convertible preferred stock warrant liability	6,590	1,073
Changes in operating assets and liabilities:		
Accounts receivable	593	3,155
Prepaid expenses and other current assets and deposits	(1,698)	171
Accounts payable and accrued liabilities	<u>501</u>	<u>(3,093)</u>
Net cash (used) provided in operating activities	(18,774)	2,773

**Investing Activities:**

Purchase of property and equipment	(125)	(120)
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Purchase of short-term investments	(1,852)	--
Sales of short-term investments	750	--
Maturities of short-term investments	<u>9,758</u>	<u>5,893</u>
Net cash provided by investing activities	8,531	5,773

**Financing Activities:**

Proceeds from exercise of stock options	582	8
Proceeds from exercise of warrant	1,537	--
Proceeds from loan payable	--	15,000
Proceeds from initial public offering, net of offering costs	107,634	--
Debt discount	--	(75)
Repayment of loan payable	(3,525)	(2,600)
Deferred financing costs	<u>--</u>	<u>(24)</u>
Net cash provided by financing activities	<u>106,228</u>	<u>12,309</u>

Increase in cash and cash equivalents	95,985	20,855
Cash and cash equivalents, beginning of period	<u>19,906</u>	<u>13,607</u>
Cash and cash equivalents, end of period	<u>\$ 115,891</u>	<u>\$ 34,462</u>

**Supplemental cash flow information:**

Interest payments	\$ 862	\$ 170
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