Chimerix Announces Third Quarter 2015 Financial Results

November 5, 2015

Topline Data from SUPPRESS Trial of Brincidofovir for Prevention of Cytomegalovirus in Hematopoietic Cell Transplant Recipients Anticipated in Early 2016

Dosing Initiated in Phase 3 SUSTAIN and SURPASS Trials of Brincidofovir for Prevention of Cytomegalovirus Disease in Kidney Transplant Recipients

DURHAM, N.C., Nov. 5, 2015 (GLOBE NEWSWIRE) -- Chimerix (NASDAQ:CMRX), a biopharmaceutical company developing novel, oral antivirals to address unmet medical needs, today reported financial results and provided a corporate update for the third quarter of 2015.

M. Michelle Berrey, MD, MPH, President and CEO, said, "We continue to make significant progress in our clinical development programs. After completing enrollment in our pivotal SUPPRESS trial in June for the prevention of clinically significant cytomegalovirus (CMV) infection in patients undergoing hematopoietic cell transplant (HCT), we have now initiated our Phase 3 SUSTAIN and SURPASS trials of brincidofovir for prevention of CMV disease in kidney transplant recipients. We remain keenly focused on delivering topline data from SUPPRESS in early 2016, preparing the New Drug Application (NDA), and continuing our commercial prelaunch initiatives for brincidofovir, which, if approved, would be the first and only therapy for the prevention of CMV in these patients who are immunocompromised following HCT."

Recent Company Highlights

- **Dosing Initiated in Phase 3 SUSTAIN and SURPASS Trials of Brincidofovir for Prevention of Cytomegalovirus Disease in Kidney Transplant Recipients**

  In October 2015, the company initiated dosing in its Phase 3 kidney transplant program. The SUSTAIN and SURPASS trials are evaluating brincidofovir for the prevention of CMV disease in kidney transplant recipients.

  SUSTAIN is designed to demonstrate the safety and efficacy of brincidofovir for the prevention of CMV disease in kidney transplant recipients at high risk of CMV disease. It is a blinded, non-inferiority study of brincidofovir versus valganciclovir in kidney transplant recipients who have not been previously infected with CMV (CMV seronegative recipient, or "R-") and who have no immunity to CMV. These CMV seronegative patients who receive a kidney from a CMV seropositive ("D+") donor are at high risk of CMV infection and disease. The trial is expected to enroll approximately 750 patients with 1:1 randomization to brincidofovir or valganciclovir for 200 days following the transplant.

  SURPASS is a blinded study of brincidofovir versus valganciclovir in kidney transplant recipients who are CMV seropositive ("R+"). These CMV seropositive patients are at an increased risk of CMV disease. The trial is expected to enroll approximately 520 patients with 1:1 randomization to brincidofovir or valganciclovir for 100 days following the transplant.

  The primary endpoint of both studies is CMV disease, with secondary endpoints related to renal function, a measurement closely correlated with long-term kidney graft survival. The same dose of brincidofovir that was studied in the SUPPRESS trial in HCT recipients, 100 mg twice-weekly, will be studied in the SUSTAIN and SURPASS trials.

- **BARDA Contract Extension of $13 Million for the Continued Development of Brincidofovir for Smallpox**

  In September 2015, the company executed an extension of its contract with the Biomedical Advanced Research and Development Authority (BARDA) for the development of brincidofovir as a medical countermeasure to treat smallpox. This latest contract extension provides approximately $13 million in additional funding. The company initiated the development contract with BARDA in February 2011 to support early research and development of brincidofovir in animal models of smallpox.

- **Completed Enrollment of Brincidofovir AdVise Trial for the Treatment of Adenovirus Infection**

  In August 2015, the company completed enrollment of its AdVise trial, which is evaluating brincidofovir for the treatment of adenovirus (AdV) infections in pediatric and adult patients. The AdVise trial enrolled over 200 patients with serious adenovirus infections, including patients in the key population of HCT recipients with disseminated AdV disease, a life-threatening infection that has reported mortality of up to 80%. HCT recipients with localized or asymptomatic AdV infection were also enrolled in AdVise, as were patients with other reasons for immune suppression that had confirmed serious adenovirus infections, a group that included solid organ transplant recipients and patients receiving chemotherapy. All patients enrolled in AdVise receive brincidofovir orally twice-weekly for 12 weeks, and are followed up to 24 weeks after treatment, with a primary endpoint of overall survival. The company is also conducting Study 305 to obtain clinical outcomes data in patients considered matched controls from the same medical centers as AdVise participants. As the company's initial NDA submission will be CMV only, the company now plans to conduct the adenovirus analysis at study conclusion, when all subjects have completed 24 weeks of follow-up after dosing with brincidofovir. The company will continue to prepare data from the AdVise trial and the historical matched controls to review with the FDA to determine the regulatory pathway for the treatment of adenovirus. Release of final results of the AdVise trial with matching controls is planned for the second half of 2016.

- **Brincidofovir Demonstrated a Statistically Significant Survival Benefit in a Pivotal Study in an Animal Model of**

Smallpox Infection

In July 2015, the company reported positive results from the pivotal smallpox study that was conducted under the FDA's Animal Efficacy Rule, which allows for testing of investigational drugs in animal models to support effectiveness in diseases which are not ethical or feasible to study in humans. In this well-characterized model of smallpox, animals were administered a lethal inoculum of rabbitpox virus, and monitored for clinical signs of disease. Following the onset of the first clinical sign of disease, animals were randomized to receive placebo, immediate brincidofovir, or brincidofovir after a delay of 24, 48, or 72 hours. The study met its primary endpoint of survival benefit with 100% of the animals that received brincidofovir immediately following the confirmation of their first clinical sign of infection surviving the disease. Further, animals treated with brincidofovir 24 or 48 hours following the first clinical sign of disease also demonstrated a statistically significant (p &#60 0.05) reduction in mortality compared to animals that received placebo.

Third Quarter 2015 Financial Results

Chimerix reported a net loss of $32.4 million, or $0.70 per basic and diluted share, for the third quarter of 2015. During the same period in 2014, the company recorded a net loss of $17.0 million, or $0.47 per basic and diluted share.

Revenues for the third quarter of 2015 increased to $2.3 million compared to $1.2 million for the same period in 2014, due to an increase in the third quarter of 2015 in reimbursable expenses associated with the company's ongoing development contract with BARDA.

Research and development expenses increased to $26.4 million for the third quarter of 2015, compared to $13.3 million for the same period in 2014. This increase was primarily due to the effect of costs related to the ongoing Phase 3 SUPPRESS trial and the AdVise trial, as well as costs for the Phase 3 SUSTAIN and SURPASS trials, and growth of the company's clinical, regulatory, development, and manufacturing groups.

General and administrative expenses increased to $8.6 million for the third quarter of 2015, compared to $4.7 million for the same period in 2014. The increase was primarily due to increased commercialization and compensation expense and the growth in the company's infrastructure.

Loss from operations was $32.7 million for the third quarter of 2015, compared to a loss from operations of $16.9 million for the same period in 2014. The variance was primarily due to the increased research and development, and general and administrative expenses, as previously discussed.

Chimerix's balance sheet at September 30, 2015 included $378.4 million of capital available to fund operations, $0.4 million in debt and approximately 46.1 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 2015 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 65612276.

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 an oral nucleotide analog that has shown in vitro antiviral activity against all five families of DNA viruses that affect humans, including the herpesviruses and adenovirus. Brincidofovir has not been associated with kidney or bone marrow toxicity in over 1,000 patients treated to date. Based on the clinically and statistically significant Phase 2 results in CMV prevention, Chimerix initiated the 450 patient Phase 3 SUPPRESS trial, which completed enrollment in June 2015. If positive, data from SUPPRESS will support Chimerix's initial regulatory submission for brincidofovir for the prevention of CMV infection in adult HCT recipients. Chimerix is also conducting AdVise, a trial in patients with adenovirus infection, an often-fatal viral infection with no approved treatment; AdVise completed enrollment in August 2015. Chimerix initiated dosing in the two Phase 3 SUSTAIN and SURPASS trials in recipients of kidney transplants, a population that continues to have unmet medical need in prevention of CMV. Chimerix is working with BARDA to develop brincidofovir as a medical countermeasure against smallpox. Brincidofovir has received Fast Track designation from the FDA for CMV, adenovirus, and smallpox.

About Chimerix

Chimerix is a biopharmaceutical company dedicated to discovering, developing and commercializing novel, oral antivirals to address unmet medical needs. Chimerix's proprietary lipid conjugate technology has produced brincidofovir, a clinical-stage nucleotide analog, CMX157 which was licensed to ContraVir Pharmaceuticals in 2014, and early clinical candidates including CMX669. 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 the FDA and other regulatory authorities may not approve brincidofovir or brincidofovir-based regimens in the currently anticipated timelines or at all, and 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 in the currently anticipated timelines. These risks, uncertainties and other factors could cause actual results to differ materially from those referred to in the forward-looking statements. The reader is cautioned not to rely on these forward-looking statements. These and other risks are described in detail in Chimerix's Quarterly Report on Form 10-Q for the quarter ended June 30, 2015, as filed with the U.S. Securities and Exchange Commission. All forward-looking statements are based on information currently available to Chimerix, and Chimerix assumes no obligation to update any such forward-looking statements.

CHIMERIX, INC.

CONSOLIDATED BALANCE SHEETS

(in thousands, except share and per share data)

(unaudited)

	September 30, 2015	December 31, 2014
ASSETS		
Current assets:		
Cash and cash equivalents	$ 44,720	$ 128,462
Short-term investments, available-for-sale	176,080	106,114
Accounts receivable	525	106
Prepaid expenses and other current assets	8,183	2,775
Total current assets	229,508	237,457
Long-term investments	159,486	52,973
Property and equipment, net of accumulated depreciation	2,439	1,310
Other long-term assets	75	138
Total assets	$ 391,508	$ 291,878
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 12,919	$ 5,938
Accrued liabilities	7,782	6,833
Loan payable, net	375	4,296
Total current liabilities	21,076	17,067
Long-term liabilities	221	175
Total liabilities	21,297	17,242
Commitments and contingencies	—	—
Stockholders' equity:		
Preferred stock, $0.001 par value, 10,000,000 shares authorized at September 30, 2015 and December 31, 2014; no shares issued and outstanding as of September 30, 2015 and December 31, 2014	—	—
Common stock, $0.001 par value, 200,000,000 shares authorized at September 30, 2015 and December 31, 2014; 46,142,340 and 41,031,770 shares issued and outstanding as of September 30, 2015 and December 31, 2014, respectively	46	41
Additional paid-in capital	671,380	496,602
Accumulated other comprehensive gain, net	356	35
Accumulated deficit	(301,571)	(222,042)
Total stockholders' equity	370,211	274,636
Total liabilities and stockholders' equity	$ 391,508	$ 291,878

CHIMERIX, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(in thousands, except share and per share data)

(unaudited)

	Three Months Ended September 30,		Six Months Ended September 30,	
	2015	**2014**	**2015**	**2014**
Revenues:				
Contract revenue	$ 2,271	$ 1,185	$ 6,104	$ 2,884
Collaboration and licensing revenue	—	—	1,548	—
Total revenues	2,271	1,185	7,652	2,884
Operating expenses:				
Research and development	26,406	13,328	65,611	29,712
General and administrative	8,613	4,717	22,068	11,812
Total operating expenses	35,019	18,045	87,679	41,524
Loss from operations	(32,748)	(16,860)	(80,027)	(38,640)
Other income (expense):				
Interest income (expense), net	299	(91)	498	(425)
Net loss	(32,449)	(16,951)	(79,529)	(39,065)
Other comprehensive loss:				
Unrealized (loss) gain on investments, net	(1,448)	(43)	321	(63)
Comprehensive loss	$ (33,897)	$ (16,994)	$ (79,208)	$ (39,128)
Per share information:				
Net loss, basic and diluted	$ (0.70)	$ (0.47)	$ (1.84)	$ (1.26)
Weighted-average shares outstanding, basic and diluted	46,059,112	35,845,792	43,112,314	30,939,752

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Source: Chimerix, Inc.