May 9, 2016

Chimerix Announces Top-Line Interim AdVise Data and First Quarter 2016 Financial Results

- Maintains strong financial position with $314.5 million in capital at quarter end -

- Company to hold conference call at 8:30am ET today -

DURHAM, N.C., May 09, 2016 (GLOBE NEWSWIRE) -- Chimerix (NASDAQ:CMRX), a biopharmaceutical company developing novel antivirals to address unmet medical needs, today reported top-line results from an interim analysis of the AdVise trial of brincidofovir for serious adenovirus (AdV) infection and other corporate updates including financial results for the first quarter ended March 31, 2016.

"We are pleased to share top-line results today from AdVise, which show a rapid antiviral effect in patients with adenovirus infection, and a correlation of viral response to mortality at day 90 and week 24 in patients with disseminated infection," said M. Michelle Berrey, MD, MPH, President and Chief Executive Officer. "Brincidofovir has demonstrated antiviral activity across a range of viral diseases with limited treatment options. We remain committed to determining the optimal use of brincidofovir in key indications, including the development of intravenous brincidofovir, which is expected to enter clinical studies in the third quarter of 2016. With strong financial resources and patent exclusivity until 2034, we are well-positioned to advance our brincidofovir development program toward potential regulatory decisions."

Company Highlights:

AdVise trial and brincidofovir program for treatment of adenovirus
Today, Chimerix provided topline results from an interim analysis of week 24 data from AdVise which shows a strong antiviral effect which was correlated with overall survival. The company is working closely with medical advisors to plan a prospective, comparative trial in patients with serious adenovirus (AdV) infection.

In August 2015, the Company completed enrollment of the AdVise trial of brincidofovir (BCV) as a treatment for serious AdV infection. Pediatric and adult patients who have undergone allogeneic hematopoietic cell transplants (HCT) are at especially high risk for serious or fatal AdV infections due to profound immunodeficiency. Mortality rates of 50 to 80 percent have been reported in the literature for disseminated AdV disease. Rates of AdV infection with virus detected in the blood or other body fluids are higher in pediatric transplant recipients than in adults, and have resulted in many medical centers instituting screening protocols to detect AdV infection before the virus causes serious disease. There is currently no approved therapy for AdV infection, and although progression to disseminated disease in pediatric HCT recipients occurs in a small proportion of patients with AdV viremia, mortality rates for pediatric patients with confirmed AdV disease is greater than 50 percent in the first three months after diagnosis.

Pediatric and adult patients who were enrolled in the AdVise study were placed into Cohort A, B, or C based on their underlying immunodeficiency and extent of AdV disease:

- Cohort A - allogeneic HCT recipients with asymptomatic or limited AdV infection
- Cohort B - allogeneic HCT recipients with disseminated AdV disease
- Cohort C - autologous HCT recipients, solid organ transplant recipients, and other immunocompromised patients

All subjects enrolled in the AdVise trial received 12 weeks of open-label oral brincidofovir, and are followed for 24 weeks after completing treatment. Final data will include follow-up through week 36 (24 weeks after the last dose of BCV), and will be available in the second half of 2016.

Top-line results from the AdVise trial at week 24 include the following:

- BCV rapidly reduced AdV levels in the blood (viral load to a level below the limit of detection) in a majority of these highly immunocompromised patients, even in patients who had previously received cidofovir. Rapid reductions in AdV viral load were correlated with improved survival at day 90 and at week 24 following diagnosis in pediatric patients.

- Two-thirds of the subjects in AdVise Cohort B (disseminated AdV disease) were pediatric allogeneic HCT recipients. Pediatric subjects had a 32 percent all-cause mortality at day 90, and 42 percent all-cause mortality at week 24. There was a smaller group of adult allogeneic HCT recipients in Cohort B, and AdV diagnoses occurred in patients with less evidence of immune reconstitution (lower lymphocyte count) than in pediatric patients. In adults, all-cause mortality at day 90 was 57 percent and at week 24 was 71 percent.
- Importantly, treatment discontinuations due to gastrointestinal (GI) adverse effects were low (8 percent), particularly in pediatric subjects (4 percent). Treatment discontinuations due to graft-versus-host-disease (GVHD) were low in both pediatric and adult patients (3 percent each). The overall safety profile of brincidofovir was consistent with prior trials, including no apparent drug-related nephrotoxicity or myelosuppression.
- Despite a rigorous attempt to collect historic controls from the same medical centers as patients from AdVise, the baseline risk factors for the control patients as assessed by medical reviewers did not reflect the high-risk patients enrolled in AdVise and thus did not provide a valid comparison for outcomes. Controls were selected based upon age, transplant type, and presence or absence of disseminated AdV infection. However, other unmatched characteristics known to confer an increased risk of AdV-related mortality, such as confirmed end-organ AdV disease, low lymphocyte count, and GVHD, were less frequent in the matched controls. A meaningful difference in overall survival between AdVise and the historic controls was thus not observed.
- In the absence of a valid comparator cohort for the open-label data from AdVise, the company is planning a prospective, comparative trial of brincidofovir in AdV that will allow stratification of patients based on risk factors for outcomes. The Company plans to meet with the U.S. Food and Drug Administration (FDA) in the coming months to review data from the interim analyses of AdVise and to discuss the regulatory pathway for brincidofovir in AdV, including the design of a potential comparative trial. A similar review is also planned with European regulators.
- Brincidofovir for the treatment of AdV continues to be available through the expanded access Study CMX001-351 (NCT 02596997) and through an Emergency IND or foreign equivalent, with approximately 100 patients treated to-date in 2016.

W. Garrett Nichols, MD, MS, Chimerix's Chief Medical Officer said, "The recently completed AdVise trial is the largest clinical study ever conducted in serious adenovirus infections. The risk factors and predictors of improved survival in pediatric and adult patients with adenovirus disease identified from the prior studies of brincidofovir in adenovirus infection, and now further informed by data from AdVise, will guide the design of a comparative trial of brincidofovir as a potential treatment for adenovirus infection."

Intravenous (IV) formulation of brincidofovir expected to enter clinic in the third quarter of 2016
Chimerix is advancing an IV formulation of brincidofovir as a potential candidate for the prevention and treatment of CMV and BK virus in HCT and kidney transplant recipients. An IND application for the IV formulation of BCV is anticipated to be filed with the FDA in the third quarter of 2016, with initial clinical studies expected to begin soon thereafter. Preclinical results to date have demonstrated the potential to decrease the GI side effects of orally-administered brincidofovir, which could be advantageous in the critical first weeks after HCT when the GI tract is recovering from conditioning chemotherapy.

Second smallpox efficacy study to be conducted in the second half of 2016
Brincidofovir is in development for the treatment of smallpox under the FDA's Animal Rule, which allows for the conduct of efficacy studies in animal models for conditions that are not appropriate for study in human subjects. In February 2016, Chimerix presented positive results from a pivotal study of brincidofovir in the rabbit model for smallpox at the American Society for Microbiology Biodefense and Emerging Diseases Research Meeting in Arlington, Virginia. The Company expects to conduct a second animal efficacy study for oral brincidofovir for smallpox in the second half of 2016, to be followed by a meeting with the FDA to discuss any additional data that may be required for a regulatory decision for brincidofovir for the treatment of smallpox.

Regulatory update provided on brincidofovir for the prevention of cytomegalovirus (CMV)
Following a review of the results from the Phase 3 trial of brincidofovir for prevention of CMV in HCT recipients and discussion with the FDA in early 2016, Chimerix elected to close the SUSTAIN and SURPASS trials for prevention of CMV disease in kidney transplant recipients. The oral brincidofovir IND for CMV prevention is currently on a partial clinical hold, pending completion of additional analyses of the SUPPRESS data and subsequent submission to the FDA.

Orphan Medicinal Product Designation granted from European Commission
In late April, the European Commission issued a positive decision for an orphan drug designation for brincidofovir for the prevention of cytomegalovirus disease. Companies that obtain orphan designation benefit from a number of incentives in the European Union, including scientific advice specific for designated orphan medicines and market exclusivity for 10 years with an additional two years for medicines that have complied with an agreed pediatric investigation plan.

First Quarter 2016 Financial Results
Chimerix reported a net loss of $26.3 million, or $0.57 per basic and diluted share, for the first quarter of 2016. During the same period in 2015, the company recorded a net loss of $22.3 million, or $0.54 per basic and diluted share.

Revenues for the first quarter of 2016 were consistent at $1.2 million compared to $1.2 million for the same period in 2015.

Revenue during these periods related to reimbursable expenses associated with the company's ongoing development contract with the Biomedical Advanced Research and Development Authority (BARDA).

Research and development expenses increased to $20.9 million for the first quarter of 2016, compared to $17.4 million for the same period in 2015. This increase was primarily due to increased employee-related compensation and benefits, the effect of costs related to the Phase 3 SUSTAIN and SURPASS trials, partially offset by a reduction in costs for the Phase 3 SUPPRESS trial and an increase related to the development of the IV formulation and the expanded access brincidofovir program.

General and administrative expenses increased to $6.9 million for the first quarter of 2016, compared to $6.1 million for the same period in 2015. The increase was primarily due to increased employee-related compensation and benefits offset by a reduction in commercialization expense.

Loss from operations was $26.6 million for the first quarter of 2016, compared to a loss from operations of $22.3 million for the same period in 2015. The variance was primarily due to the increased research and development, and general and administrative expenses, as previously discussed.

Chimerix's balance sheet at March 31, 2016 included $314.5 million of capital available to fund operations, no debt, and approximately 46.2 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 first quarter 2016 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 99330956.

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 Chimerix
Chimerix is a biopharmaceutical company dedicated to discovering, developing and commercializing novel 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 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. 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 Current Report on Form 8-K 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)

	March 31, 2016	December 31, 2015
ASSETS		
Current assets:		
Cash and cash equivalents	$ 27,503	$ 20,605
Short-term investments, available-for-sale	235,832	199,729
Accounts receivable	566	2,432
Prepaid expenses and other current assets	4,904	6,071
Total current assets	268,805	228,837
Long-term investments	52,363	124,040
Property and equipment, net of accumulated depreciation	3,006	3,045
Other long-term assets	64	70
Total assets	$ 324,238	$ 355,992
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 3,568	$ 10,458
Accrued liabilities	6,638	9,721
Total current liabilities	10,206	20,179
Deferred rent	331	354
Total liabilities	10,537	20,533
Stockholders' equity:		
Preferred stock, $0.001 par value, 10,000,000 shares authorized at March 31, 2016 and December 31, 2015; no shares issued and outstanding as of March 31, 2016 and December 31, 2015	—	—
Common stock, $0.001 par value, 200,000,000 shares authorized at March 31, 2016 and December 31, 2015; 46,210,768 and 46,162,525 shares issued and outstanding as of March 31, 2016 and December 31, 2015, respectively	46	46
Additional paid-in capital	679,672	675,591
Accumulated other comprehensive loss, net	(343)	(764)
Accumulated deficit	(365,674)	(339,414)
Total stockholders' equity	313,701	335,459
Total liabilities and stockholders' equity	$ 324,238	$ 355,992

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

	Three Months Ended March 31,	
	2016	2015
Contract revenue	$ 1,228	$ 1,238
Operating expenses:		
Research and development	20,936	17,444
General and administrative	6,924	6,123
Total operating expenses	27,860	23,567
Loss from operations	(26,632)	(22,329)
Other income (expense):		
Interest income, net	372	63
Net loss	(26,260)	(22,266)

Other comprehensive loss:		
Unrealized gain on investments, net	421	625
Comprehensive loss	$ (25,839)	$ (21,641)
Per share information:		
Net loss, basic and diluted	$ (0.57)	$ (0.54)
Weighted-average shares outstanding, basic and diluted	46,184,134	41,220,989

Primary Logo

Source: Chimerix, Inc.

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