



**CHIMERIX**

August 6, 2015

## **Chimerix Announces Second Quarter 2015 Financial Results**

*Targeted Enrollment Now Completed for Brincidofovir SUPPRESS and AdVise Trials*

*Statistically Significant Survival Benefit Demonstrated in Brincidofovir Pivotal Study in Animal Model of Smallpox Infection*

DURHAM, N.C., Aug. 6, 2015 (GLOBE NEWSWIRE) -- Chimerix (NASDAQ:CMRX), a biopharmaceutical company developing novel, oral antivirals in areas of high unmet medical need, today reported financial results and provided a corporate update for the second quarter of 2015.

M. Michelle Berrey, MD, MPH, President and CEO, said, "We are very pleased with the key milestones that we have achieved for brincidofovir and the company. We recently reported a statistically significant survival benefit for brincidofovir in a pivotal study in an animal model of smallpox, an important step toward a potential FDA approval of brincidofovir as the first antiviral treatment for smallpox. We completed our target enrollment for both clinical Phase 3 SUPPRESS and AdVise trials, and strengthened our financial position by completing an offering of common stock. The transplant community is increasingly recognizing the frequency of serious viral infections and in particular the cumulative impact of these viral infections on the twenty percent non-relapse mortality in allogeneic HCT. We are diligently preparing for availability of data from SUPPRESS and AdVise in early 2016 and, if positive, the brincidofovir NDA and MAA to follow."

### **Recent Company Highlights**

- **Completed Enrollment of Brincidofovir Phase 3 SUPPRESS Trial for Prevention of CMV Infection**

In June 2015, the company completed enrollment of the targeted 450 subjects in SUPPRESS, a Phase 3 trial evaluating brincidofovir for the prevention of clinically significant cytomegalovirus (CMV) infection in hematopoietic cell transplant (HCT) recipients. The company anticipates reporting topline data from SUPPRESS in early 2016.

The primary endpoint of SUPPRESS is prevention of clinically significant CMV infection through the first 24 weeks post-transplant. Subjects were randomized to receive brincidofovir or placebo orally twice-weekly for the first 14 weeks following their HCT, and are followed for 10 weeks after treatment. If the primary endpoint for SUPPRESS is achieved, brincidofovir could be the first antiviral approved for the prevention of CMV infection in stem cell transplant recipients.

Secondary endpoints in SUPPRESS could provide important data on the potential for brincidofovir to prevent clinically significant infections with other DNA viruses that often coexist in immunocompromised patients such as adenovirus, Epstein-Barr virus (EBV) and BK virus, and the potential impact of brincidofovir on overall and transplant-related mortality in the critical first months following the transplant.

- **Completed Enrollment of Brincidofovir Phase 3 AdVise Trial for the Treatment of Adenovirus Infection**

Earlier this week, the company completed enrollment of its Phase 3 AdVise Study, 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 over 100 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 for a minimum of 12 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.

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

In July 2015, the company reported 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. At the time of 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. Animals treated with brincidofovir upon the first clinical sign of disease and animals that receive brincidofovir 24 or 48 hours after the first clinical sign of disease demonstrated a statistically significant ( $p < 0.05$ ) reduction in mortality compared to animals that received placebo. Final results from this study are expected in the fourth quarter of 2015 and will be submitted to an upcoming medical conference and to the FDA for a discussion regarding further development requirements.

- **Successful Offering of Common Stock**

In June 2015, the company completed a common stock offering with net proceeds of approximately \$162 million. These proceeds are expected to be used primarily to fund the company's Phase 3 trials of brincidofovir in kidney transplant recipients, expansion of commercial manufacturing, pre-launch commercial activities, additional research and development programs, and general corporate purposes.

## **Second Quarter 2015 Financial Results**

Chimerix reported a net loss of \$24.8 million, or \$0.59 per basic and diluted share, for the second quarter of 2015. During the same period in 2014, the company recorded a net loss of \$11.7 million, or \$0.39 per basic and diluted share.

Revenues for the second quarter of 2015 increased to \$4.1 million compared to \$0.9 million for the same period in 2014, due to an increase in the second quarter of 2015 in reimbursable expenses associated with the company's ongoing development contract with Biomedical Advanced Research and Development Authority (BARDA), and the recognition of deferred revenue related to the Company's collaboration and licensing agreement with ContraVir Pharmaceuticals.

Research and development expenses increased to \$21.8 million for the second quarter of 2015, compared to \$8.1 million for the same period in 2014. This increase was primarily due to the effect of costs related to the ongoing Phase 3 SUPPRESS and Advise trials, start-up costs for the Phase 3 SUSTAIN and SURPASS trials, and growth of the company's clinical, regulatory and development groups.

General and administrative expenses increased to \$7.3 million for the second quarter of 2015, compared to \$4.4 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 \$25.0 million for the second quarter of 2015, compared to a loss from operations of \$11.6 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 June 30, 2015 included \$404.3 million of capital available to fund operations, \$1.5 million in debt and approximately 45.8 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 second 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 91132559.

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, 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 Phase 3 trial in patients with adenovirus infection, an often-fatal viral infection with no approved treatment; Advise completed enrollment in August 2015. Chimerix intends to initiate enrollment in two Phase 3 trials in recipients of kidney transplants, a population that continues to have unmet medical need in prevention of CMV and BKV, among other dsDNA viral infections. 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 in areas of high unmet medical need. Chimerix's proprietary lipid conjugate technology has produced brincidofovir (CMX001), 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](http://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 March 31, 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)

|   | <u>June 30,</u><br><u>2015</u> | <u>December 31,</u><br><u>2014</u> |
|---|--------------------------------|------------------------------------|
| <b>ASSETS</b>   |                                |                                    |
| Current assets:   |                                |                                    |
| Cash and cash equivalents                               | \$ 127,776                     | \$ 128,462                         |
| Short-term investments, available-for-sale              | 130,555                        | 106,114                            |
| Accounts receivable                                     | 2,311                          | 106                                |
| Prepaid expenses and other current assets               | 8,651                          | 2,775                              |
| Total current assets                                    | 269,293                        | 237,457                            |
| Long-term investments                                   | 150,139                        | 52,973                             |
| Property and equipment, net of accumulated depreciation | 1,996                          | 1,310                              |
| Other long-term assets                                  | 80                             | 138                                |
| Total assets  | <u>\$ 421,508</u>              | <u>\$ 291,878</u>                  |
| <b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>             |                                |                                    |
| Current liabilities:                                    |                                |                                    |
| Accounts payable  | \$ 9,819                       | \$ 5,938                           |
| Accrued liabilities                                     | 10,758                         | 6,833                              |
| Loan payable, net                                       | 1,484                          | 4,296                              |
| Total current liabilities                               | 22,061                         | 17,067                             |
| Long-term liabilities                                   | 134                            | 175                                |
| Total liabilities                                       | 22,195                         | 17,242                             |
| Commitments and contingencies                           | —                              | —                                  |
| Stockholders' equity:                                   |                                |                                    |

|  |                   |                   |
|--|-------------------|-------------------|
| Preferred stock, \$0.001 par value, 10,000,000 shares authorized at June 30, 2015 and December 31, 2014; no shares issued and outstanding as of June 30, 2015 and December 31, 2014                                    | —                 | —                 |
| Common stock, \$0.001 par value, 200,000,000 shares authorized at June 30, 2015 and December 31, 2014; 45,847,032 and 41,031,770 shares issued and outstanding as of June 30, 2015 and December 31, 2014, respectively | 46                | 41                |
| Additional paid-in capital   | 666,586           | 496,602           |
| Accumulated other comprehensive gain, net  | 1,803             | 35                |
| Accumulated deficit  | <u>(269,122)</u>  | <u>(222,042)</u>  |
| Total stockholders' equity   | <u>399,313</u>    | <u>274,636</u>    |
| Total liabilities and stockholders' equity   | <u>\$ 421,508</u> | <u>\$ 291,878</u> |

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

|  | <u>Three Months Ended June 30,</u> |                    | <u>Six Months Ended June 30,</u> |                    |
|--|------------------------------------|--------------------|----------------------------------|--------------------|
|  | <u>2015</u>                        | <u>2014</u>        | <u>2015</u>                      | <u>2014</u>        |
| <b>Revenues:</b>                                       |                                    |                    |                                  |                    |
| Contract revenue                                       | \$ 2,598                           | \$ 919             | \$ 3,833                         | \$ 1,699           |
| Collaboration and licensing revenue                    | <u>1,545</u>                       | <u>—</u>           | <u>1,548</u>                     | <u>—</u>           |
| Total revenues   | 4,143                              | 919                | 5,381                            | 1,699              |
| <b>Operating expenses:</b>                             |                                    |                    |                                  |                    |
| Research and development                               | 21,762                             | 8,092              | 39,205                           | 16,384             |
| General and administrative                             | <u>7,332</u>                       | <u>4,423</u>       | <u>13,455</u>                    | <u>7,095</u>       |
| Total operating expenses                               | <u>29,094</u>                      | <u>12,515</u>      | <u>52,660</u>                    | <u>23,479</u>      |
| Loss from operations                                   | (24,951)                           | (11,596)           | (47,279)                         | (21,780)           |
| <b>Other income (expense):</b>                         |                                    |                    |                                  |                    |
| Interest income (expense), net                         | <u>136</u>                         | <u>(138)</u>       | <u>199</u>                       | <u>(334)</u>       |
| <b>Net loss</b>  | (24,815)                           | (11,734)           | (47,080)                         | (22,114)           |
| <b>Other comprehensive loss:</b>                       |                                    |                    |                                  |                    |
| Unrealized gain (loss) on investments, net             | <u>1,144</u>                       | <u>12</u>          | <u>1,769</u>                     | <u>(20)</u>        |
| Comprehensive loss                                     | <u>\$ (23,671)</u>                 | <u>\$ (11,722)</u> | <u>\$ (45,311)</u>               | <u>\$ (22,134)</u> |
| <b>Per share information:</b>                          |                                    |                    |                                  |                    |
| Net loss, basic and diluted                            | <u>\$ (0.59)</u>                   | <u>\$ (0.39)</u>   | <u>\$ (1.13)</u>                 | <u>\$ (0.78)</u>   |
| Weighted-average shares outstanding, basic and diluted | <u>42,079,716</u>                  | <u>30,111,380</u>  | <u>41,614,494</u>                | <u>28,446,074</u>  |

CONTACT: CHIMERIX CONTACT:

Joseph T. Schepers

Executive Director, Investor Relations and

Corporate Communications

[ir@chimerix.com](mailto:ir@chimerix.com)

919-287-4125

Source: Chimerix, Inc.

