
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

**Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934**

September 11, 2013

Date of Report (Date of earliest event reported)

Chimerix, Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction
of incorporation)

001-35867

(Commission File Number)

33-0903395

(IRS Employer Identification No.)

**2505 Meridian Parkway, Suite 340
Durham, NC**

(Address of principal executive offices)

27713

(Zip Code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligations of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
-

Item 8.01 Other Events.

On September 11, 2013, in the press release attached hereto as Exhibit 99.1 and incorporated herein by reference, we announced results from Study 202, our exploratory Phase 2 study evaluating brincidofovir (CMX001) in hematopoietic cell transplant (HCT) recipients with early adenovirus (AdV) infection. Study 202 is the first trial of an antiviral agent in AdV infection. Brincidofovir is an investigational oral nucleotide analog lipid-conjugate that has demonstrated broad-spectrum activity in vitro against all pathogenic families of double-stranded DNA (dsDNA) viruses, including herpesviruses, adenoviruses, and polyomaviruses.

The information in this Item 8.01 and the attached Exhibit 99.1 is being furnished and shall not be deemed “filed” for the purposes of Section 18 of the Securities and Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section. The information in this Item 8.01 and the attached Exhibit 99.1 shall not be incorporated by reference into any registration statement or other document pursuant to the Securities Act of 1933, as amended.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release of Chimerix, Inc. dated September 11, 2013.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Chimerix, Inc.

Dated: September 11, 2013

By: /s/ Timothy W. Trost

Timothy W. Trost

Senior Vice President, Chief Financial Officer and Corporate Secretary

INDEX TO EXHIBITS

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release of Chimerix, Inc. dated September 11, 2013.



Chimerix Presents Brincidofovir (CMX001) Adenovirus Phase 2 Results

Positive Phase 2 Study Results Presented as Late Breaker at ICAAC

DURHAM, NC, September 11, 2013 – Chimerix, Inc. (NASDAQ: CMRX), a biopharmaceutical company developing novel, oral antivirals in areas of high unmet medical need, today announced the results from its exploratory Phase 2 Study 202 evaluating brincidofovir (CMX001) in hematopoietic cell transplant (HCT) recipients with early adenovirus (AdV) infection. Study 202 was the first trial of an antiviral agent in AdV infection. Brincidofovir (CMX001) is an investigational oral nucleotide analog lipid-conjugate that has demonstrated activity against all pathogenic families of double-stranded DNA (dsDNA) viruses, including herpesviruses, adenoviruses, and polyomaviruses.

Michael Grimley, MD, Associate Professor of Clinical Pediatrics in the Division of Bone Marrow Transplant and Immune Deficiency at Cincinnati Children's Hospital Medical Center, and the lead investigator in Chimerix's Phase 2 AdV study, presented the trial results during the "Viral Infections in Immunosuppressed Hosts" session at the 53rd Annual Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC) meeting on September 10, 2013 in Denver, CO.

"These data strongly support the continued development of CMX001 as a global prevention for dsDNA viruses, a leading cause of non-relapse mortality in the months following a transplant," said Dr. Grimley.

Although AdV in HCT recipients has been recognized as a severe and often-fatal infection in pediatric and adult patients who have undergone recent HCT, there are no approved antiviral treatments. Potential risk factors associated with an increased risk of rapid progression to AdV infection have been identified in the scientific literature, but the frequency of AdV in the blood or AdV disease was unknown prior to this trial. Early data from patients who had received CMX001 for AdV infection through Emergency Investigational New Drug (EIND) regulations had provided anecdotal evidence of improved outcomes compared with historic data. This exploratory Phase 2 trial was designed to initiate CMX001 or placebo during early AdV infection, prior to symptomatic disease, and to evaluate the potential to decrease AdV viral load or prevent progression to AdV disease.

Results: Safety and tolerability data from this 48-subject trial confirmed the lack of hematologic and renal toxicity for once-weekly (QW) or twice-weekly (BIW) CMX001 dosed for 6-12 weeks, and showed the successful implementation of the Safety Monitoring and Management Plan (SMMP) to address gastrointestinal side effects reported in earlier trials. Temporary dose interruptions for grade 3 diarrhea were successfully utilized in the trial, with one permanent discontinuation for diarrhea in the CMX001 QW cohort. Three additional discontinuations in the trial were reported for abdominal pain (CMX001 BIW cohort), lower GI hemorrhage (CMX001 BIW cohort), and severe rash (placebo cohort). No new serious safety issues were identified in this trial, and no changes were necessary in the safety monitoring in the recently initiated Phase 3 SUPPRESS trial for prevention of CMV.

Efficacy outcomes for Study 202 were progression to possible or probable AdV disease or significant changes in AdV viremia. Although statistical significance was not achieved, numerical benefit was demonstrated for CMX001 100 mg BIW for multiple endpoints:

- **Virologic Response:** Subjects exposed to CMX001 100 mg BIW demonstrated a significant rapid decrease in levels of AdV in the blood (viremia) versus subjects in the CMX001 QW and placebo cohorts. In subjects who entered the trial with higher levels of AdV viremia ($VL > 3.0 \log_{10}$ copies/mL) viral decline on CMX001 BIW was consistent for seven of eight (7 of 8, 88%) subjects, all suppressing AdV levels to below the limit of detection ($LOD = 2.0 \log_{10}$ copies/mL, 100 copies/mL) within the first week of dosing, versus only one of eight (13%) high-level viremia subjects in the placebo cohort.

CHIMERIX, INC.
2505 Meridian Parkway, #340
Durham, NC 27713

Tel: (919) 806-1074
Fax: (919) 806-1146



- **Treatment Failures:** Three of 14 (21%) subjects enrolled in the CMX001 BIW cohort were considered treatment failures with increasing AdV viremia or progression to AdV disease, versus six of 16 (38%) subjects in the CMX001 QW cohort, and six of 18 (33%) subjects in the placebo cohort.
- **Mortality:** Overall mortality was lower for the subjects in the CMX001 BIW cohort (2 of 14, 14%) versus the CMX001 QW (5 of 16, 31%) and placebo (7 of 18, 39%) cohorts.

Adenovirus in the blood was chosen as a potential early indicator of AdV disease based on the accepted clinical utility of viremia as an early trigger for initiation of antiviral therapy for CMV in these patients. Results from this study bring into question whether AdV viremia is an indicator of early AdV disease. For low-level AdV viremia ($< 3.0 \log_{10}$ copies/mL), a significant proportion of subjects spontaneously cleared viremia prior to initiation of therapy or during placebo therapy. These data indicate that low level AdV viremia may be a transient phenomenon in some subjects. In contrast, high level AdV viremia ($\geq 3.0 \log_{10}$ copies/mL) at screening was often associated with rapid development of symptoms and end-organ disease even before therapy could be started. Further research is needed to identify clinical indicators of early AdV disease which could be used for early intervention, but prevention of AdV continues to be the preferred strategy through which diseases caused by dsDNA viruses can be avoided.

“The acceptable safety and tolerability of CMX001, and successful incorporation of the Safety Monitoring and Management Plan in this study, were important milestones for the brincidofovir program as we initiate dosing in the Phase 3 SUPPRESS trial for CMV prevention in HCT recipients,” said M. Michelle Berrey, MD, MPH, Chief Medical Officer of Chimerix. “Additionally, consistent trends toward decreased progression of AdV disease and a decrease in overall mortality for subjects randomized to CMX001 BIW reaffirm our belief that earlier intervention in viral disease is the preferred strategy to decrease morbidity and mortality from AdV and other dsDNA viral diseases. Ultimately, we believe that broad use of CMX001 as a prevention for CMV, AdV, and other viral diseases that impact immunocompromised patients will prove to be the best approach.”

Summary of CMX001 Study 202 Results Presented at ICAAC

CMX001 BIW initiated at the time of detection of AdV viremia showed potential clinical benefit in reducing progression to AdV disease and all-cause mortality. Subset analyses of disease progression and all-cause mortality were consistent in trends favoring the CMX001 BIW regimen over placebo or CMX001 QW. A greater proportion of subjects randomized to CMX001 BIW achieved undetectable levels of AdV viremia during randomized therapy and a lower proportion of subjects on the BIW regimen progressed to symptomatic disease compared to placebo or CMX001 QW.

CMX001 Study 202 Design

Study 202 was a randomized, blinded, placebo-controlled proof-of-concept trial assessing the use of CMX001 as a preemptive therapy for AdV infection. HCT recipients were randomized into the study upon appearance of detectable AdV viremia but before the appearance of symptoms of AdV disease. Subjects were randomized to one of three dosing regimens: CMX001 BIW, CMX001 QW or placebo. Forty-eight pediatric and adult subjects were randomized into the trial beginning in June 2011.

The design of the study was based on the limited information available on the natural history of AdV infection in immunocompromised subjects, preliminary and uncontrolled data available on the activity of CMX001 against AdV, ethical considerations due to the placebo-controlled design and high mortality associated with AdV disease in HCT recipients and epidemiologic data indicating a low incidence of AdV viremia in subjects post-HCT.

CHIMERIX, INC.
2505 Meridian Parkway, #340
Durham, NC 27713

Tel: (919) 806-1074
Fax: (919) 806-1146



About Brincidofovir (CMX001)

Brincidofovir is an investigational oral nucleotide analog lipid-conjugate that has shown broad-spectrum antiviral activity against all five families of dsDNA viruses that affect humans, including herpesviruses such as CMV, adenoviruses, polyomaviruses such as BKV, papillomaviruses, and orthopoxviruses. Brincidofovir has a favorable safety and tolerability profile, with no evidence of kidney or bone marrow toxicity in over 900 patients dosed with brincidofovir for prevention, preemptive therapy, or treatment of dsDNA viruses that cause disease in humans.

In a Phase 2 trial of 230 HCT recipients, brincidofovir demonstrated potential clinical utility in prevention of CMV infection. In this same CMV trial, brincidofovir-treated subjects had improvements in kidney function and hematuria (blood in the urine) when compared to placebo-treated subjects, suggesting that brincidofovir may reduce BKV-associated bladder and renal damage.

On September 9, 2013, Chimerix announced the initiation of its Phase 3 SUPPRESS trial evaluating 100mg CMX001 BIW for the prevention of CMV in HCT recipients.

About Hematopoietic Cell Transplantation (HCT)

HCT is a medical procedure performed most frequently for hematology and oncology indications to treat patients with certain cancers of the blood and bone marrow, such as multiple myeloma or leukemia, or genetic diseases. For these patients, replacement of the blood forming system is the best therapeutic alternative. Because of chemotherapy and immunosuppressants that are used before, during and after the procedure, patients are highly susceptible to viral, bacterial and fungal infections and associated complications related to the chemotherapy and immunosuppression. These post-transplant complications are a significant cause of morbidities and mortalities following the procedure.

About Chimerix

Chimerix, a biopharmaceutical company based in Durham, NC, 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. Brincidofovir has shown broad-spectrum activity against dsDNA viruses, including herpesviruses, adenoviruses and polyomaviruses. On September 9, 2013, Chimerix announced the initiation of its Phase 3 SUPPRESS trial evaluating 100mg CMX001 BIW for the prevention of CMV in HCT recipients. Chimerix's second product candidate, CMX157, an oral nucleotide analog for the treatment of HIV infection, was licensed to Merck in July 2012.

CHIMERIX, INC.
2505 Meridian Parkway, #340
Durham, NC 27713

Tel: (919) 806-1074
Fax: (919) 806-1146



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 Chimerix’s Phase 3 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 SUPPRESS; the demonstrated efficacy of brincidofovir in the SUPPRESS trial; 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 recent Quarterly Report on Form 10-Q, 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 CONTACT:

Joseph T. Schepers
Executive Director, Investor Relations and Corporate Communications
jschepers@chimerix.com
919-287-4125

MEDIA CONTACT:

Tony Plohoros
tplohoros@6degreespr.com
908-940-0135

CHIMERIX, INC.

2505 Meridian Parkway, #340
Durham, NC 27713

Tel: (919) 806-1074
Fax: (919) 806-1146
