

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 9, 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)

Registrant's telephone number, including area code: (919) 806-1074

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 9, 2013, we announced in the press release attached hereto as Exhibit 99.1 and incorporated herein by reference, that Chimerix has initiated dosing in the Phase 3 SUPPRESS Trial (ClinicalTrials.gov ID: NCT01769170) of brincidofovir (CMX001) for Prevention of Cytomegalovirus in Hematopoietic Cell Transplant Recipients. SUPPRESS is evaluating brincidofovir for the prevention of cytomegalovirus (CMV) infection, the most significant infectious disease in hematopoietic cell transplant (HCT) recipients. Brincidofovir is an investigational oral nucleotide analog lipid-conjugate that has demonstrated activity against all pathogenic 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

Exhibit No.	Description
99.1	Press Release of Chimerix, Inc. dated September 9, 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 9, 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 9, 2013.



Chimerix Initiates Phase 3 SUPPRESS Trial of Brincidofovir (CMX001) for Prevention of Cytomegalovirus in Hematopoietic Cell Transplant Recipients

DURHAM, NC, September 9, 2013 – Chimerix, Inc. (NASDAQ: CMRX), a biopharmaceutical company developing novel, oral antivirals in areas of high unmet medical need, today announced initiation of dosing in the Phase 3 SUPPRESS trial (ClinicalTrials.gov ID: NCT01769170). SUPPRESS is evaluating brincidofovir (CMX001) for the prevention of cytomegalovirus (CMV) infection, the most significant infectious disease in hematopoietic cell transplant (HCT) recipients. Brincidofovir is an investigational oral nucleotide analog lipid-conjugate that has demonstrated activity against all pathogenic double-stranded DNA (dsDNA) viruses, including herpesviruses, adenoviruses, and polyomaviruses.

“Initiation of our Phase 3 SUPPRESS trial marks a significant milestone in the development program for brincidofovir,” said Kenneth I. Moch, President and CEO of Chimerix. “A well-tolerated and effective prevention for CMV disease in hematopoietic cell transplant patients remains an important unmet medical need, as existing antiviral therapies are limited by significant hematologic and renal toxicities.”

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 prevention 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 evidence of other dsDNA viruses, including adenovirus (AdV), varicellovirus (VZV), BK virus (BKV), and other herpesviruses such as HHV-6, which 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 of the 450 enrolled subjects receiving twice weekly (BIW) brincidofovir versus placebo (2-to-1 ratio). 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 in the Phase 2 trial of brincidofovir and other recent trials of investigational antivirals for CMV prevention. The ability to begin prevention during the early post-transplant period may decrease the risk of CMV infection in transplant patients.

Subjects enrolled in SUPPRESS will receive brincidofovir or placebo from the early post-transplant period through Week 14 post-transplant, the period of highest risk for viral reactivation. Enrolled subjects will continue to be monitored for evidence of CMV reactivation and other dsDNA viral infections through Week 24 post-transplant. The recently approved Roche TAQMAN® real-time polymerase chain reaction assay will be used to monitor levels of CMV in the blood. Approximately 40 transplant centers will participate in SUPPRESS.

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

“Initiation of patient dosing in SUPPRESS advances the development program for brincidofovir, which has the potential to make a meaningful difference in the lives of immunocompromised patients,” said M. Michelle Berrey, MD, MPH, Chief Medical Officer of Chimerix. “Because transplant patients are too often faced with the clinical consequences of multiple dsDNA viral infections, brincidofovir with its broad spectrum antiviral activity has the potential to improve overall outcomes in patients undergoing HCT, through both direct and indirect effects of prevention of CMV and other dsDNA viral infections.”



In addition to the ongoing Phase 3 SUPPRESS trial, Chimerix has recently announced top line data from a Phase 2 trial of brincidofovir for AdV infection in pediatric and high-risk adult HCT recipients. Results from this trial will be presented as a late-breaker at the annual ICAAC Conference on September 10, 2013.

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. 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. In September 2013, Chimerix initiated the Phase 3 SUPPRESS trial for the prevention of CMV in HCT recipients. Chimerix recently announced top line data from its Phase 2 trial in pediatric and adult HCT recipients evaluating brincidofovir as a preemptive therapy for AdV disease, an often fatal infection with no approved therapies. These data, which will be presented at the annual ICAAC conference, support continued development of brincidofovir as a broad-spectrum antiviral therapy for CMV and AdV. 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.

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

CMV is a member of the herpesvirus family and 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 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. Chimerix's second product candidate, CMX157, an oral nucleotide analog for the treatment of HIV infection, was licensed to Merck in July 2012.

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
919-287-4125

MEDIA CONTACT:

Tony Plohoros
tplohoros@6degreespr.com
