
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 26, 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))
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Item 8.01 Other Events.

On September 26, 2013, in the press release attached hereto as Exhibit 99.1 and incorporated herein by reference, we announced the publication of positive results from our Phase 2 Study CMX001-201 evaluating brincidofovir (CMX001) for the prevention of cytomegalovirus (CMV) infection in hematopoietic cell transplant (HCT) recipients. The article, entitled “CMX001 to Prevent Cytomegalovirus Disease in Hematopoietic-Cell Transplantation,” appears in the September 26th issue of the *New England Journal of Medicine* (N Engl J Med 369:1227-36).

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 26, 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 26, 2013

By: /s/ Timothy W. Trost

Timothy W. Trost

Senior Vice President, Chief Financial Officer and Corporate Secretary

INDEX TO EXHIBITS

Exhibit No.	Description
99.1	Press Release of Chimerix, Inc. dated September 26, 2013.



Chimerix Announces Publication of Positive Phase 2 Results of Brincidofovir (CMX001) in the *New England Journal of Medicine*

Phase 2 Trial Evaluated Brincidofovir for the Prevention of Cytomegalovirus (CMV) Infection in Hematopoietic Cell Transplant Recipients

DURHAM, NC, September 26, 2013 – Chimerix, Inc. (NASDAQ: CMRX), a biopharmaceutical company developing novel, oral antivirals in areas of high unmet medical need, today announced the publication of results from its Phase 2 Study CMX001-201 evaluating brincidofovir (CMX001) for the prevention of cytomegalovirus (CMV) infection in hematopoietic cell transplant (HCT) recipients. The article, entitled “CMX001 to Prevent Cytomegalovirus Disease in Hematopoietic-Cell Transplantation,” appears in the September 26th issue of the *New England Journal of Medicine* (N Engl J Med 369:1227-36).

Brincidofovir, Chimerix’s lead product candidate, is an investigational oral nucleotide analog lipid-conjugate that has shown broad-spectrum antiviral activity against double-stranded DNA (dsDNA) viruses including CMV. Study CMX001-201, a 230-subject, randomized, placebo-controlled, double-blind, dose-escalation study, met the primary endpoint of reduction in CMV viremia and/or CMV disease for brincidofovir 100 mg twice weekly versus placebo ($p=0.002$). Based on these positive Phase 2 results, Chimerix recently initiated the Phase 3 SUPPRESS trial of brincidofovir 100 mg twice weekly for the prevention of CMV infection in HCT recipients.

“Although prevention of CMV infection has been recognized as a superior approach to decrease CMV-related morbidity and mortality in the months following hematopoietic cell transplantation, the side effects of available antivirals have precluded their approval and use in this setting,” said M. Michelle Berrey, MD, MPH, Chief Medical Officer of Chimerix. “The significant decrease in CMV events and lack of hematologic and renal toxicity shown in Study CMX001-201 provided the supportive data to allow us to progress brincidofovir into the Phase 3 SUPPRESS trial.”

CMX001-201 Study Results

The primary endpoint for Study CMX001-201 was the incidence of CMV disease at any time during therapy or a CMV polymerase chain reaction (PCR) assay result of greater than 200 copies/mL (the lower limit of quantification of the assay) at the time of the last dose of study drug. All brincidofovir doses and dose regimens demonstrated antiviral activity when compared to placebo, with the exception of the lowest dose, 40 mg once weekly. The proportion of subjects who developed CMV disease or a CMV PCR positive result at the end of the 100 mg twice weekly dosing period was 10% (five of 50) versus 37% (22 of 59) in the placebo-treated group ($p=0.002$).

In a pre-specified subgroup of subjects who were CMV PCR negative at baseline (the subject population being enrolled in SUPPRESS), zero of 41 subjects in the brincidofovir 100 mg twice weekly group developed CMV PCR of $\geq 1,000$ copies/mL during the dosing period, compared to 15 of 47 subjects (32%) in the placebo group ($p<0.001$). The twice weekly dosing regimen was more effective than the same total dose given once weekly, leading to the selection of the 100 mg twice weekly dosing regimen for further development in SUPPRESS.

In subjects who received brincidofovir, there was no evidence of kidney or bone marrow toxicity, both associated with available anti-CMV therapies. Diarrhea was the most frequent adverse event in the Phase 2 study and was addressed with a safety management algorithm in the final cohort, which reduced the number of discontinuations due to diarrhea and allowed a majority of subjects to complete the intended course of therapy. The safety management algorithm has been incorporated in subsequent brincidofovir studies including the ongoing SUPPRESS trial.

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CMX001-201 Study Design

Study CMX001-201 was a randomized, double-blind, placebo-controlled, dose-escalation multi-center Phase 2 trial evaluating the safety, tolerability and efficacy of CMX001 to prevent or control CMV disease in 230 allogeneic HCT recipients at high risk of CMV infection. Following engraftment, or evidence of successful production of new blood cells by the new bone marrow, subjects were randomized into five sequential, dose-escalating cohorts to receive either brincidofovir or placebo, at doses ranging from 40 mg once weekly to 200 mg twice weekly. Subjects were treated for nine to 11 weeks through post-transplant Week 13, after which subjects were followed for an additional four to eight weeks.

About Brincidofovir (CMX001)

Chimerix's lead product candidate, brincidofovir (CMX001), is an oral nucleotide analog that has shown broad-spectrum antiviral activity against all five families of dsDNA viruses that affect humans, including cytomegalovirus (CMV), adenovirus (AdV), BK virus and herpes simplex viruses. Chimerix initiated the Phase 3 SUPPRESS trial of brincidofovir for the prevention of CMV infection in the third quarter of 2013. SUPPRESS will support Chimerix's initial regulatory submission for prevention of CMV infection in adult HCT recipients. At the Annual ICAAC Conference in September 2013, Chimerix presented positive data from its Phase 2 trial evaluating brincidofovir as a preemptive therapy for AdV, an often-fatal infection with no approved treatment.

About the Phase 3 SUPPRESS Trial

The Phase 3 SUPPRESS trial of brincidofovir (CMX001) 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 clinical events and other evidence of dsDNA viral infections, 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 100 mg 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. 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.

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About Hematopoietic Cell Transplantation (HCT)

HCT (also known as bone marrow transplantation) is a medical procedure performed 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. Chemotherapy and radiation used to kill any cancer cells before the transplant can leave patients susceptible to viral, bacterial and fungal infections and associated complications, a significant cause of morbidities and mortalities following HCT.

About Chimerix

Chimerix 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. 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 the clinical development and use 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 the SUPPRESS trial; the demonstrated efficacy of brincidofovir in the SUPPRESS trial; the accuracy of Chimerix's estimates regarding expenses and capital requirements; regulatory developments in the United States and foreign countries; Chimerix's ability to obtain and maintain intellectual property protection for brincidofovir; and the loss of key scientific or management personnel. These and other risks and uncertainties 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, as filed with 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.

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