

Edgar Filing: CHIMERIX INC - Form 8-K

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 December 28, 2015, Chimerix, Inc. (the “*Company*”) announced that its Phase 3 SUPPRESS trial of brincidofovir in patients undergoing hematopoietic cell transplantation (“*HCT*”) did not achieve its primary endpoint for the prevention of clinically significant cytomegalovirus (“*CMV*”) infection through Week 24 after transplant.

During the on-treatment period through Week 14 after HCT, fewer patients in the brincidofovir arm had a CMV infection, consistent with the positive antiviral effect of the compound seen in the Phase 2 study. However, during the 10 weeks off treatment from Week 14 to Week 24, there was an increase in CMV infections in the brincidofovir arm compared to the control arm. There was also a non-statistically significant increase in mortality in the brincidofovir arm compared to the control arm. Preliminary analysis suggests that the primary endpoint failures in both the prevention of CMV infections and mortality in the brincidofovir arm were driven by confirmed cases of graft-versus-host-disease (“*GVHD*”), which resulted in a significantly higher use of corticosteroids than in the control arm. Both GVHD and use of corticosteroids are risk factors for “late” CMV infection that occurs after discontinuation of the antiviral in HCT recipients.

A full analysis of the SUPPRESS trial results is ongoing and will be presented by the Company at the BMT Tandem Meetings in Honolulu, Hawaii, to be held on February 18-22, 2016.

The Company plans to continue the programs testing brincidofovir in serious adenovirus infections and in smallpox. Pending the availability of complete data from SUPPRESS, including secondary endpoints in other dsDNA viral infections, the Company has elected to pause further enrollment in the Phase 3 SUSTAIN and SURPASS trials in kidney transplant recipients.

Forward-Looking Statements

Statements contained in this Current Report on Form 8-K 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. Risks are described more fully in the Company’s filings with the Securities and Exchange Commission, including without limitation the Company’s most recent Quarterly Report on Form 10-Q 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.

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: December 28, 2015

By: /s/ Timothy W. Trost
Timothy W. Trost
Senior Vice President,
Chief Financial Officer
and Corporate
Secretary