
**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

Date of Report (Date of earliest event Reported): September 19, 2016

Vical Incorporated

(Exact Name of Registrant as Specified in Charter)

DELAWARE

(State or Other Jurisdiction of Incorporation)

000-21088

(Commission File Number)

93-0948554

(I.R.S. Employer Identification Number)

10390 Pacific Center Court, San Diego, California 92121-4340

(Address of Principal Executive Offices) (Zip Code)

(858) 646-1100

(Registrant's telephone number, including area code)

Not Applicable

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation 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 19, 2016, Vical Incorporated and Astellas Pharma Inc. announced topline results from a randomized, double-blind, placebo-controlled Phase 2 study evaluating the safety and efficacy of cytomegalovirus (CMV) vaccine, ASP0113, versus placebo in kidney transplant patients receiving an organ from a CMV-seropositive donor. Results from the study demonstrated that the trial did not meet its primary endpoint, which was the proportion of patients having CMV viremia defined as a plasma viral load of ≥ 1000 IU/mL by central laboratory assay through one year after first injection of study drug. Additionally, the secondary endpoints of CMV-associated disease and CMV-specific antiviral therapy, which were evaluated by an independent, blinded Adjudication Committee, were similar in both treatment groups. The safety profiles were generally similar between treatment groups. However, local injection site reactions were more common in the ASP0113 treatment group.

The randomized, double-blind, placebo-controlled trial evaluated the safety and efficacy of ASP0113 in CMV-seronegative kidney transplant recipients receiving an organ from a CMV-seropositive donor (D+/R-). Enrollment included 150 kidney transplant recipients across approximately 80 centers in North America, Europe and Australia and randomized 1:1 to receive either ASP0113 or placebo, in addition to valganciclovir or ganciclovir prophylaxis for 100 days after kidney transplant.

The Phase 3 study of ASP0113 in hematopoietic cell transplant (HCT) recipients is on-going and has completed target enrollment.

Item 9.01. Financial Statements and Exhibits.

Exhibit 99.1. Press release dated September 19, 2016

SIGNATURE

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.

Vical Incorporated

Date: September 19, 2016

By: /s/ Vijay B. Samant
Vijay B. Samant
Chief Executive Officer

Vical and Astellas Announce Topline Results from a Phase 2 Study of Investigational Cytomegalovirus (CMV) Vaccine (ASP0113) in Kidney Transplant Patients

SAN DIEGO and TOKYO, Sept. 19, 2016 (GLOBE NEWSWIRE) -- Vical Incorporated (Nasdaq:VICAL) and Astellas Pharma Inc. (TOKYO:4503) today announced topline results from a randomized, double-blind, placebo-controlled Phase 2 study evaluating the safety and efficacy of cytomegalovirus (CMV) vaccine, ASP0113, versus placebo in kidney transplant patients receiving an organ from a CMV-seropositive donor. Results from the study demonstrated that the trial did not meet its primary endpoint, which was the proportion of patients having CMV viremia defined as a plasma viral load of ≥ 1000 IU/mL by central laboratory assay through one year after first injection of study drug. Additionally, the secondary endpoints of CMV-associated disease and CMV-specific antiviral therapy, which were evaluated by an independent, blinded Adjudication Committee, were similar in both treatment groups.

The safety profiles were generally similar between treatment groups. However, local injection site reactions were more common in the ASP0113 treatment group. Further detailed data from the trial is expected to be disclosed at an upcoming scientific congress.

"The unmet medical need in addressing CMV infection in transplant patients remains high. Although we had hoped for a different outcome, we look forward to further analyzing these data in hopes of contributing knowledge to the future development programs in this patient population," said Bernhardt G. Zeiher, M.D., President, Development, Astellas. "In addition, we continue to focus on execution of our Phase 3 study in hematopoietic cell transplant (HCT) recipients and are pleased to announce that we have met our target enrollment."

"We are pleased with our collaborative relationship with Astellas, and we look forward to the results from the pivotal Phase 3 study in HCT recipients, which we expect to obtain during the fourth quarter of 2017," said Vijay Samant, President and Chief Executive Officer, Vical.

About the Study

The randomized, double-blind, placebo-controlled trial evaluated the safety and efficacy of ASP0113 in CMV-seronegative kidney transplant recipients receiving an organ from a CMV-seropositive donor (D+/R-). Enrollment included 150 kidney transplant recipients across approximately 80 centers in North America, Europe and Australia and randomized 1:1 to receive either ASP0113 or placebo, in addition to valganciclovir or ganciclovir prophylaxis for 100 days after kidney transplant.

About ASP0113

ASP0113 is a vaccine designed to prevent CMV disease and associated complications in SOT and HCT recipients. The bivalent DNA vaccine encodes CMV phosphoprotein 65 and glycoprotein B antigens for induction of both cellular and humoral immune responses, formulated with a proprietary poloxamer-based delivery system. ASP0113 was initially developed by Vical and is now in partnership with Astellas for further development and commercialization. ASP0113 has received Orphan Drug Designation in the United States and Europe for the prevention of CMV disease in SOT and HCT recipients. The ongoing Phase 3 trial of ASP0113 in HCT recipients represents the first time a CMV vaccine or a DNA vaccine has entered Phase 3 testing in a registrational trial.

About CMV

CMV is a herpes virus that infects more than half of all adults in the United States by age 50, and is even more widespread in developing countries. A healthy immune system typically protects an infected person against CMV disease, but does not prevent or clear latent infection. Individuals whose immune systems are not fully functional are at high risk of CMV reactivation, potentially leading to severe illness or death. Those at greatest risk include HCT and SOT recipients, as well as infants born to mothers who first become infected during pregnancy.

About Astellas

Astellas Pharma Inc., based in Tokyo, Japan, is a company dedicated to improving the health of people around the world through the provision of innovative and reliable pharmaceutical products. We focus on Urology, Oncology, Immunology, Nephrology and Neuroscience as prioritized therapeutic areas while advancing new therapeutic areas and discovery research leveraging new technologies/modalities. We are also creating new value by combining internal capabilities and external expertise in the medical/healthcare business. Astellas is on the forefront of healthcare change to turn innovative science into value for patients. For more information, please visit our website at www.astellas.com/en.

About Vical

Vical develops biopharmaceutical products for the prevention and treatment of chronic or life-threatening infectious diseases, based on its patented DNA delivery technologies and other therapeutic approaches. Additional information on Vical is available at www.vical.com.

Vical Forward-Looking Statements

This press release contains forward-looking statements subject to risks and uncertainties that could cause actual results to differ materially from those projected. Forward-looking statements include anticipated developments in collaborative programs, including the timing of data from the pivotal Phase 3 study of ASP0113 in HCT recipients. Risks and uncertainties include whether Vical or others will continue development of ASP0113; whether any product candidates will be shown to be safe and efficacious in clinical trials; whether Vical is able to continue its collaborative arrangements or enter into new ones; the timing of clinical trials; whether Vical or its collaborative partners will seek or gain approval to market any product candidates; and additional risks set forth in the Company's filings with the Securities and Exchange Commission. These forward-looking statements represent the Company's judgment as of the date of this release. The Company disclaims, however, any intent or obligation to update these forward-looking statements.

Astellas Cautionary Notes

In this press release, statements made with respect to current plans, estimates, strategies and beliefs and other statements that are not historical facts are forward-looking statements about the future performance of Astellas. These statements are based on management's current assumptions and beliefs in light of the information currently available to it and involve known and unknown risks and uncertainties. A number of factors could cause actual results to differ materially from those discussed in the forward-looking statements. Such factors include, but are not limited to: (i) changes in general economic conditions and in laws and regulations, relating to pharmaceutical markets, (ii) currency exchange rate fluctuations, (iii) delays in new product launches, (iv) the inability of Astellas to market existing and new products effectively, (v) the inability of Astellas to continue to effectively research and develop products accepted by customers in highly competitive markets, and (vi) infringements of Astellas' intellectual property rights by third parties.

Information about pharmaceutical products (including products currently in development) which is included in this press release is not intended to constitute an

advertisement or medical advice.

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