Vaxart Reports Topline Results from Phase 2 Trial of Teslexivir™ for the Treatment of Condyloma

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Safety and tolerability profile comparable to placebo

Primary efficacy endpoint not achieved - Positive trend in two important subgroups

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Jun. 4, 2018-- Vaxart, Inc., a clinical-stage biotechnology company developing oral recombinant vaccines that are administered by tablet rather than by injection, today reported the topline results from a Phase 2 clinical trial evaluating the safety and efficacy of an antiviral teslexivir 5% gel dosed topically twice daily in 218 subjects for the treatment of condyloma, or anogenital warts. The primary efficacy endpoint was defined as complete clearance of baseline condyloma by week 16.

Analysis of the topline data demonstrated the study met all its primary safety objectives, with teslexivir showing a benign safety and tolerability profile, comparable to placebo. Adverse events and local skin reactions in the teslexivir group were also comparable with placebo, with mostly mild adverse events in both groups. No serious adverse events were observed. Early treatment termination, which we consider an important marker of product tolerability, was minimal with only 1.4% of patients discontinuing in either group.

With respect to the primary efficacy endpoint, 30.6% of patients in the teslexivir group completely cleared baseline condyloma by week 16, compared to 23.3% of patients in the placebo group. The difference was not statistically significant. In preliminary subgroup analysis, the rate of complete baseline condyloma clearance trended higher in female patients (37.5% teslexivir versus 23.3% placebo) and in patients with large condylomas (30.0% teslexivir versus 15.4% placebo), although results were not significant in either group.

“While this trial did not achieve the primary efficacy endpoint, we were pleased with the benign safety profile and positive efficacy trends in certain patient subpopulations,” said Wouter Latour, chief executive officer of Vaxart. “We are currently in the follow-up phase of the study and data collection should continue for a few more weeks. During this period, we will conduct further analysis of the results, which should inform us about the future steps with the teslexivir program. In the meantime, we will continue to focus on the advancement of our oral vaccine platform through the clinic.”

A number of patients remain in the 3 month follow-up assessment period of the study. Following the completion of the last patient visit in the follow-up recurrence assessment period and the cleaning and lock of that portion of the study, Vaxart will report on the recurrence efficacy endpoints.

About the Teslexivir Trial

This teslexivir trial was a Phase 2 double-blind, randomized, placebo-controlled trial designed to evaluate the safety, tolerability and efficacy of teslexivir 5% gel in male and female patients with condyloma, or anogenital warts. 218 female and male patients with 2-30 external condyloma were randomized in a 2:1 ratio, with randomization stratified on gender, to be dosed twice daily for up to 16 weeks with teslexivir or placebo gel. Condyloma and local skin tolerability were measured and assessed by investigators at study visits occurring 2, 4, 6, 9, 12 and 16 weeks following randomizations and initiation of dosing. If subjects cleared all condyloma prior to the end of 16 weeks, they proceeded directly to the 3-month untreated safety follow-up phase to assess for condyloma recurrence. The primary efficacy endpoint was to determine the complete clearance rate for baseline anogenital warts from the commencement of therapy to the end of the treatment period. Secondary efficacy endpoints include various assessments of clearance, time to clearance, and wart area reduction for both baseline warts and post-baseline emergent warts (i.e. all condyloma).

Teslexivir is a topical antiviral agent that is a potent and selective inhibitor of the interaction between two essential viral proteins, E1 and E2, an interaction that is a necessary step for human papilloma virus (HPV) DNA replication and thus viral production.

About Condyloma (Anogenital Warts)

Condyloma infections from HPV represent the most frequent viral sexually transmitted disease in adults worldwide, with >95% of condyloma caused by HPV 6 and 11. In the United States, approximately one to two percent of sexually active adults between the ages of 15 to 49 develop condyloma as the primary clinical manifestation of HPV infection. Currently available treatments for anogenital warts typically are divided into two categories, ablative/destructive therapies and topical therapies. Existing topical therapies are associated with significant mucosal toxicities manifesting as erosions and ulcerations, which can result in therapy discontinuation. Ablative options can be painful and scarring, and can lead to sexual dysfunction. Another significant limitation with current therapies is a high incidence of recurrence after successful primary treatment.

About Vaxart

Vaxart is a clinical-stage biotechnology company focused on developing oral recombinant protein vaccines based on its proprietary oral vaccine platform. Vaxart’s vaccines are designed to generate broad and durable immune responses that protect against a wide range of infectious diseases and may be useful for the treatment of chronic viral infections and cancer. Vaxart’s vaccines are administered using a convenient room temperature-stable tablet, rather than by injection. Vaxart believes that tablet vaccines are easier to distribute and administer than injectable vaccines and have the potential to significantly increase vaccination rates. Vaxart’s development programs include oral tablet vaccines that are designed to protect against norovirus, seasonal influenza and respiratory syncytial virus (RSV), as well as a therapeutic vaccine for human papillomavirus (HPV). Vaxart is also developing several small-molecule antiviral drug candidates, including teslexivir (BTA074), an antiviral treatment for condyloma caused by HPV types 6 and 11. For more information, please visit www.vaxart.com.

Note Regarding Forward-Looking Statements

This press release contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of

historical facts, included in this press release regarding our strategy, prospects, plans and objectives, beliefs and expectations of management are forward-looking statements. These forward-looking statements may be accompanied by such words as “believe,” “could,” “potential” and other words and terms of similar meaning. Examples of such statements include, but are not limited to, statements relating to the Vaxart’s ability to develop and commercialize its product candidates. Vaxart may not actually achieve the plans, carry out the intentions or meet the expectations or projections disclosed in our forward-looking statements and you should not place undue reliance on these forward-looking statements. Actual results or events could differ materially from the plans, intentions, expectations and projections disclosed in the forward-looking statements. Various important factors could cause actual results or events to differ materially from the forward-looking statements that Vaxart makes, that Vaxart’s product candidates may not be approved by the FDA or non-U.S. regulatory authorities; that, even if approved by the FDA or non-U.S. regulatory authorities, Vaxart’s product candidates may not achieve broad market acceptance; and the risks described from time to time in the reports Vaxart files with the Securities and Exchange Commission, or SEC, including its Form 10-Q for the three months ended March 31, 2018. Copies of reports filed with the SEC are posted on Vaxart’s website and are available from Vaxart without charge. Vaxart does not assume any obligation to update any forward-looking statements, except as required by law.

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