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Vaxart Announces Positive Phase 1 Study of Oral Norovirus Vaccine

First Oral Vaccine Meets All Safety and Immunogenicity Endpoints

*Vaccine was Well Tolerated and Generated
Significant Systemic and Mucosal Immune Responses in All Dose Groups*

SOUTH SAN FRANCISCO, Calif., February 14, 2017 - Vaxart, Inc., a clinical-stage biotechnology company developing oral recombinant vaccines that are administered by tablet rather than by injection, announced today that its norovirus tablet vaccine met the primary and secondary endpoints for safety and immunogenicity in a Phase 1 clinical trial.

“The norovirus Phase 1 results are an important milestone for our oral vaccine platform as well as for the entire vaccine space,” said Dave Liebowitz, MD, PhD, chief medical officer of Vaxart. “Building on results from previous studies, the tablet vaccine platform has been well tolerated across multiple indications, and we consistently see robust and broad responses for our candidate vaccines. The norovirus results are particularly striking as they were obtained with a single dose of our tablet vaccine.”

The norovirus tablet vaccine was well tolerated in all subjects. Solicited symptoms and unsolicited adverse events were mostly mild in severity with no serious adverse events (SAEs) reported in the study to date. The vaccine also met its immunogenicity endpoint in both dose groups, as measured by a significant increase in the norovirus blocking antibody titers (BT₅₀) in serum. Significant mucosal immune responses were observed as well, and the vaccine generated potent gut homing, memory, and plasmablast B cell activation.

“The norovirus tablet vaccine combines ease of oral delivery with a novel mode of immunization that induces both a local intestinal immune response as well as a systemic antibody response. As a result, the norovirus tablet vaccine generates rapid, robust intestinal immune responses against norovirus,” said Sean Tucker, PhD, chief scientific officer of Vaxart. “We believe that the generation of a potent immune response at the same site as the actual norovirus infection will serve as an effective first line of defense, and may provide better cross protection against divergent strains than serum antibody responses alone.”

About the Study Design

The randomized, double-blind, placebo-controlled Phase 1 dose-ranging study assessed the safety and immunogenicity of Vaxart's norovirus (GI.1, Norwalk) tablet vaccine in 66 healthy adult volunteers, with 46 of the subjects immunized with a single dose of the oral tablet vaccine at two different dose levels and 20 subjects given placebo tablets.

About Norovirus

Norovirus is recognized as a leading cause of acute gastroenteritis. It is a common intestinal infection that typically lasts three to five days and is marked by watery diarrhea, vomiting, abdominal cramps, nausea and sometimes fever. Symptoms can be more severe in older adults and young children and may lead to serious complications including death. Norovirus causes frequent and widespread outbreaks in the military, food industry, travel industry, child care facilities, elderly homes and healthcare facilities.

The U.S. Centers for Disease Control and Prevention (CDC) estimates that norovirus causes 19 to 21 million illnesses in the United States each year, resulting in 56,000 to 71,000 hospitalizations and 570 to 800 deaths. In a recent John Hopkins University study, researchers estimated healthcare costs of norovirus at \$4.2 billion and lost productivity costs at \$56.2 billion globally.

Currently there are no norovirus vaccines approved by the U.S. Food and Drug Administration. For further information on norovirus, its burden on human health and vaccine development, please visit the websites of the CDC <http://www.cdc.gov/norovirus/> and the Public Library of Science <http://collections.plos.org/norovirus>.

About Vaxart

Vaxart is a clinical-stage company developing tablet vaccines based on its proprietary oral vaccine platform. Its lead development programs are oral tablet vaccines designed to protect against Norovirus, seasonal influenza and respiratory syncytial virus (RSV). Vaxart vaccines are administered using convenient room temperature-stable tablets that can be stored and shipped without refrigeration, and eliminate the risk of needle-stick injury and medical waste associated with injectable vaccines. For more information, please visit www.vaxart.com.

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