



## Vaxart Announces Publication of the Phase 1 Results of its Oral Norovirus Tablet Vaccine in Journal of Clinical Investigation Insight

July 12, 2018

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Jul. 12, 2018-- Vaxart, Inc. (Nasdaq:VXRT), a clinical-stage biotechnology company developing oral recombinant vaccines that are administered by tablet rather than by injection, today announced publication of the comprehensive results of the previously disclosed Phase 1 clinical trial with its norovirus oral tablet vaccine in the *Journal of Clinical Investigation Insight*.

The paper by Leesun, Kim, et al., "*Safety and immunogenicity of an oral tablet norovirus vaccine, a phase 1 randomized, placebo-controlled trial*", highlights the benign safety profile of the Vaxart vaccine and describes the generation of robust systemic and mucosal immune responses, including mucosal IgA, memory B cells, and serum blocking antibody titers (BT50), all potential correlates of protection.

"Our oral tablet vaccine elicited a substantial serum antibody response as well as a strong local intestinal immune response as measured by mucosal homing B-cells and a greater than tenfold increase in fecal IgA antibodies," said Sean Tucker, Ph.D., founder and chief scientific officer of Vaxart. "Local immunity in the gut is likely to be a key factor in protection against norovirus infection, and this data confirms our vaccine is uniquely positioned to generate this type of response."

The primary immunological endpoint of the study, an increase in BT50 titers, was met in the high dose group with 78% of subjects showing a greater than or equal to twofold rise after a single immunization (P=0.0003). In addition, more than 80% of recipients of the high dose vaccine developed mucosally-primed norovirus specific circulating antibody secreting cells, IgA positive memory B cells expressing the  $\alpha\beta7$  gut homing receptor, and fecal IgA.

"Norovirus causes substantial morbidity and mortality all across the globe, impacting populations of all ages in all walks of life. We believe our tablet vaccine could provide an optimal solution to help reduce the burden of disease in vulnerable populations such as the elderly and the very young, as well as people at-risk in the healthcare, travel and food industry," said David Taylor, M.D., chief medical officer of Vaxart. "We look forward to initiating our Norovirus vaccine Phase 1 safety and immunogenicity bivalent study and Phase 2 monovalent challenge study in the coming months."

### 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.

### 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 also 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). For more information, please visit [www.vaxart.com](http://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, results from preclinical and clinical trials, commercialization agreements and licenses, beliefs and expectations of management are forward-looking statements. These forward-looking statements may be accompanied by such words as "believe," "could," "potential," "will" 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 and clinical results and trial data. 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 in the "Risk Factors" sections of Vaxart's Quarterly Report filed on Form 10-Q for the quarter ended March 31, 2018 and of Vaxart's other periodic reports filed with the SEC. Vaxart does not assume any obligation to update any forward-looking statements, except as required by law.

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