

For Immediate Release

Vaxart Announces Lancet ID Publication of Influenza Tablet Vaccine Phase 1 Results

H1N1 Influenza Tablet Vaccine Demonstrates a Favorable Safety Profile and Protective Immunity

SOUTH SAN FRANCISCO, Calif., August 23, 2015 – Vaxart, Inc., a privately held, clinicalstage company developing vaccines that are administered by tablet rather than by injection, today announced that *The Lancet Infectious Diseases* published an article on the company's Phase 1 clinical trial results for its oral H1N1 influenza vaccine.

Vaxart's H1N1 influenza tablet vaccine demonstrated protective immunity based on Hemagglutinin Inhibition Assay (HAI) with HAI titer increases comparable to increases reported for currently approved influenza vaccines. HAI titers are an important standard used by industry and the U.S. Food and Drug Administration (FDA) for determining protective immunity. The Vaxart tablet vaccine also exhibited a favorable safety and tolerability profile, with only mild adverse events that were distributed evenly between the placebo and vaccine groups.

"It is very encouraging to see this level of protective immunity after just one dose of an oral flu vaccine," said Dr. William Schaffner, professor of preventive medicine and professor of medicine in the division of infectious diseases at Vanderbilt University School of Medicine in Nashville, Tenn. "These early Phase 1 study results suggest the room temperature-stable tablet vaccine may be as protective as currently marketed influenza vaccines, while offering substantial advantages in distribution and ease of administration. I look forward to the results of further expanded vaccine trials".

The H1N1 Phase 1 trial was a randomized, double-blind, placebo-controlled study that enrolled 24 healthy volunteers ages 18-49 with HAI titers of less than or equal to 1:20. Subjects received a single administration of either placebo or the Vaxart H1N1 tablet vaccine.

Four-fold or greater increases in HAI titers were observed in 92 percent of vaccinated subjects (11 of 12), with 75 percent (9 of 12) reaching protective HAI titers equal to or greater than 1:40. The Geometric Mean Titer (GMT) rose 7.7 fold in the vaccine group. In contrast, none of the subjects receiving placebo (0 of 12) seroconverted and the GMT increase was negligible.

"Our tablet vaccine elicited HAI responses to influenza in more than 90 percent of subjects, an excellent result for any influenza vaccine," said Sean Tucker, Ph.D., founder and chief scientific officer of Vaxart and senior author of *The Lancet ID* article. "In addition, our vaccine generated robust mucosal responses, suggesting that vaccines based on our platform could offer advantages over injectable vaccines in their ability to protect against mucosal pathogens such as norovirus and respiratory syncytial virus (RSV)."

"This data represents a major milestone for the Vaxart oral vaccines platform as a whole," said Dave Liebowitz, M.D., Ph.D., chief medical officer of Vaxart and first author of *The Lancet ID* article. "As we move forward with the development of our quadrivalent influenza tablet vaccine, we are advancing our norovirus and RSV tablet vaccines, which are based on the same platform, to the clinic."

About Vaxart

Vaxart is a privately held, clinical-stage company developing a broad range of vaccines based on its proprietary oral recombinant vaccines platform. Vaxart vaccines are administered using convenient room temperature-stable tablets that can be stored and shipped without refrigeration, are easy to administer, and reduce medical waste and risk of needle-stick injury associated with injectable vaccines. For more information, please visit <u>www.vaxart.com</u>.

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