

Vaxart's Tablet Vaccine for H1N1 Influenza Generates Protective Immunity Equivalent to Injectable in Phase I Clinical Study

Data Presented at World Vaccine Congress 2014 in Brussels

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Vaxart, Inc., a privately held, clinical-stage company developing recombinant vaccines that are administered by tablet rather than by injection, today announced clinical results demonstrating that its H1N1 tablet vaccine generates protective immunity comparable to currently licensed influenza vaccines, as measured by hemagglutinin inhibition assay (HAI), the established correlate of protection. Vaxart's founder and chief scientific officer, Sean Tucker, PhD, discussed the data in a presentation today at the 15th Annual World Vaccine Congress in Brussels.

"A tablet vaccine for flu could significantly change the way we administer vaccines," said John J. Treanor, MD, Chief of Infectious Diseases at the University of Rochester Medical Center. "Every year, more than 100 million Americans visit their pharmacy, clinic or private practitioner to receive a flu shot. In contrast, a tablet vaccine could be brought directly to the user, such as in the workplace or at school, and avoids the need to worry about needles. A tablet vaccine might also be manufactured and distributed faster than current injectable vaccines, a factor that could be critical when responding to a pandemic or outbreak. These results look very promising and I am eager to hear more about the continued progress of Vaxart's programs."

The data were generated in a phase 1 clinical study of Vaxart's tablet vaccine candidate for H1N1 seasonal influenza. The randomized, double-blind, placebo-controlled study enrolled 24 healthy volunteers of ages 18-49, who received either placebo or vaccine in tablet form in a single administration.

In the study, 75 percent of subjects (9 of 12) taking the Vaxart H1N1 tablet vaccine fully seroconverted as measured by HAI, a response rate equivalent to those reported for licensed injectable vaccines. HAI geometric mean titers increased 7.7-fold, also within the range of injectable vaccines. None of the subjects receiving placebo (0 of 12) seroconverted. HAI titers are an important standard for determining protective immunity used by industry and the U.S. Food and Drug Administration (FDA).

In addition, the Vaxart H1N1 tablet vaccine induced four-fold increases in neutralizing antibody titers in 92 percent of subjects (11 of 12) as measured by microneutralization (MN) titers, an increasingly recognized marker of protective immunity, versus 0 percent (0 of 12) in the placebo group. MN geometric mean titers rose 23-fold, exceeding rate increases reported for most injectable vaccines. The vaccine also generated strong mucosal and cellular immune responses in 92 percent of

subjects, suggesting the Vaxart tablet vaccine could offer broader protection than currently licensed influenza vaccines.

The vaccine exhibited an excellent clinical safety profile, with only mild adverse events that were distributed evenly between the placebo and vaccine groups.

“Our tablet flu vaccine generated broad immune responses in more than 90 percent of recipients, while a remarkable 75 percent seroconverted by HAI, the accepted correlate for protective immunity”, said Vaxart CEO Wouter Latour, MD. “We are seeing a safety-immunogenicity profile that could compete with that of any of the currently marketed vaccines, even without taking into account the convenience and logistical advantages of our room-temperature stable and user-friendly tablet. In addition, our tablet vaccine could significantly increase vaccination rates, currently at about 45 percent of the U.S. population.”

Dr. Tucker discussed the Vaxart data in his presentation, *“High titer neutralizing antibody and potent cellular immune responses to influenza in humans after oral immunization with recombinant adenovirus expressing HA.”* He further commented, “In addition to the robust HAI and MN responses, our tablet vaccine generated strong mucosal and T cell responses in virtually all recipients (11 of 12). This suggests that the platform technology could be exploited across a wide range of vaccine indications. Accordingly, we are accelerating our non-flu programs and expect to enter the clinic with at least two new indications in 2015.”

About Vaxart’s Tablet Vaccine Technology

Vaxart produces its vaccine tablets utilizing industry-standard cell-culture and solid-dose manufacturing processes. For influenza, specifically, Vaxart expects this process would enable manufacturing and distribution of the annually updated vaccine to the public considerably faster than egg-based influenza vaccine manufacturing technologies.

The Vaxart temperature-stable tablet vaccine offers a wide range of advantages such as: convenience, acceptance, self-administration, distribution by mail, reduced cold chain requirements, elimination of needles, reduced medical waste and rapid manufacturing.

About Vaxart

Vaxart is a privately owned company developing oral recombinant vaccines based on its proprietary delivery platform. The Vaxart platform is suitable for delivering a wide range of protein vaccine antigens, such as those used in currently marketed influenza, hepatitis B and human papilloma virus (HPV) vaccines. Care Capital is the lead investor in the company and its largest shareholder. For more information, please visit www.vaxart.com.

Contacts

Vaxart

Wouter Latour, 650-550-3511

Alison Marquiss, 415-272-2389

pr-mail@vaxart.com

or

Burns McClellan, on behalf of Vaxart

Justin Jackson, 212-213-0006

jjackson@burnsmc.com