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# Norovirus Vaccine 'Meets All Endpoints in 1b Study.' What Does This Mean?

*By Josh Bloom — September 27, 2019*

No Thanks. Photo: Your Dictionary [1]

This past April I reported that Vaxart, a small San Francisco vaccine biotech, was ready to start dosing volunteers with its experimental vaccine against norovirus, aka, the stomach flu, in Phase Ib studies (See Hurdle But No Hurl: Vaxart Starts Phase Ib Norovirus Vaccine Trials [2]). Yesterday, the company announced the results and they are intriguing.

A norovirus vaccine – there isn't one at this time – would be a welcome tool to combat a very common (20 cases million/year in the US), highly infectious, and *extremely* unpleasant infection. It is rarely fatal in the US (<1,000 deaths per year) but worldwide it's a different story; 685 million people catch it each year and 50,000 children [3]will die from the resulting dehydration.

Now that the Phase Ib data are available I can tell you that 1) the numbers look good, but 2) it did not prevent one person from vomiting. This may sound a little nuts, but it makes perfect sense when you look at what information this trial was designed to reveal.

The trial included 80 healthy volunteers, who received either one of two oral **(1)** vaccines (each for a different strain of the bug) or both together. The study endpoints (measurable results) were immunogenicity (whether antibodies to the virus were generated), safety, and whether one vaccine interfered with the other. They passed with "flying colors," but we don't yet whether the vaccine will fly; it's still too soon to tell. This is because the trial was *not* designed to see whether the vaccine would protect people *who were infected* with norovirus from getting sick. No one in this trial was given a spoonful of norovirus. That comes next, assuming they can find a group of loonies willing to participate in *that* trial. As Yogi Berra once said, "include me out."

Here what it *did* do.

According to Vaxart the individual vaccines "demonstrated robust immunogenicity." The vaccine for the GI.1 strain had IgA ASC response rate of 78% **(2)**. The response to the vaccine for the GII.4 strain **(3)** was even better - 93%.

Together, they worked even better. The bivalent (both strains together) generated response rates of 86% and 90%, respectively.

These numbers are quite good. It means that the bivalent vaccine *should* offer protection against actual infection. But the proof will be in the pudding during phase II trials where the volunteers will be given the vaccine and then infected. Then we'll see if they keep the pudding down.

If so, we may really have something. If not, it won't only be the volunteers who will be suffering severe gastrointestinal distress. The company's investors won't feel so great either. Better keep a couple of mops around just in case.

NOTES:

(1) Only four vaccines are given orally at this time.

(2) IgA means "A" type antibodies, which control immunity in mucous membranes. This is important because norovirus take hold in the mucosal layer of the small intestine. ASC means antibody-secreting cells, the more the merrier.

(3) GII.4 has been the most common strain worldwide [3] since 2002. It is short for genogroup II, genotype 4. Don't ask.

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**Links**

[1] https://www.yourdictionary.com/germaphobe

[2] https://www.acsh.org/news/2019/04/17/hurdle-no-hurl-vaxart-starts-phase-ib-norovirus-vaccine-trials-13965

[3] https://www.cdc.gov/norovirus/trends-outbreaks/worldwide.html