Hurdle But No Hurl: Vaxart Starts Phase Ib Norovirus Vaccine Trials

By Josh Bloom — April 17, 2019

No need to keep the mop handy. At least yet.

Vaxart Inc., a San Francisco based vaccine biotech just announced that it would begin dosing subjects in a Phase Ib study (1) of the company's bivalent oral experimental vaccines against norovirus - the cause of the so-called "stomach flu." The two components of the vaccine, VXA-G1.1-NN and VXA-G2.4-NS will be tested in volunteers, who will receive either vaccine alone, both together, or neither.

But none of the 86 volunteers will get sick; none of them will be exposed to live virus. This trial is designed to study only the safety and immunogenicity of the vaccines, not efficacy. If the 1b trials look promising enough to continue, volunteers will be challenged with a live virus in Phase II. There may be a slightly different mindset regarding the two trials...
The trial will be conducted in two parts. Part 1 will begin with an open-label (not blinded) administration to six subjects. If there are no safety issues at day eight, the trial will then be double-blinded, and the other volunteers will receive either vaccine alone, or placebo and be monitored (for safety and immune response) for four weeks. In Part 2 the volunteers who got both vaccines in Part 1 will get a booster (open-label) four months later and be monitored for safety for one year. The vaccines are tablets, not injections.

There is no way to prevent norovirus (2), which makes life miserable for 20 million Americans every year, mostly during winter months. Treatment options are mostly limited to rehydration, maybe witchcraft. Sometimes an antiemetic drug, such as Zofran, can be helpful. Norovirus is also one of the most infectious of all pathogens, which is why it goes around schools, hospitals, nursing homes, and cruise ships so readily.

A successful vaccine would be a substantial medical advance. Norovirus is more than a nuisance; it kills 50,000 children worldwide [5] each year and the price tag for treatment and lost productivity in the US alone is $2 billion [6].

Knock ’em dead, guys.

NOTES:

(1) Phase I trials can be divided into Ia and Ib. Both trials are (usually) for safety. In Ia, volunteers get a single dose, which is raised in increments if no adverse effects are apparent. In Ib, volunteers are given multiple doses of the drug, which are also raised incrementally. Phase II volunteers are given what is expected to be therapeutic doses and efficacy is usually the endpoint.

(2) The best advice for prevention is soap and water. You and I both know that’s not good enough.