BioSpectrum
the business of Bio & Health Sciences
ASIA EDITION

Takeda gastro norovirus vaccine shows +ve results

October 7, 2013 | News | By BioSpectrum Bureau



Singapore: Takeda Pharmaceutical has achieved positive reponse from its phase I/II study of its intramuscular bivalent (GI/GII) norovirus vaccine candidate in healthy adult volunteers who were challenged with the most commonly occurring norovirus (genotype GII.4) that causes gastroenteritis.

The study demonstrated that two doses of the experimental bivalent norovirus were well tolerated, and that the candidate vaccine had a clinically relevant impact on the incidence of norovirus illness after challenge, as well as the severity in breakthrough cases. In addition to the impact on clinical illness, a positive trend toward reduction in viral shedding in stool was observed. The study also provided important information toward optimization of confirmatory lab testing for norovirus disease and infection in a future field trial.

Norovirus gastroenteritis is most commonly associated with vomiting and diarrhea, and occurs in all age groups. In the study, a statistically significant reduction in mild, moderate or severe vomiting and/or diarrhea was observed in vaccinated subjects, meeting the secondary endpoint of the study. The total number of subjects with gastroenteritis symptoms was also reduced in the vaccine group, but this reduction was not statistically significant and the primary endpoint was not met.

"Norovirus causes nearly 90 percent of epidemic non-bacterial outbreaks of gastroenteritis around the world, leading to as many as 71,000 hospitalizations each year in the US alone," said the study's lead investigator Dr David I Bernstein, and director of Infectious Diseases at Cincinnati Children's Hospital. "There is a critical unmet medical need for a vaccine to combat this significant global health issue, and this vaccine candidate has the potential to address that need."

"This is the first time that vaccination with a norovirus candidate vaccine has resulted in a reduction of symptoms caused by experimental exposure to the most common strain of norovirus, genotype GII.4. We are very encouraged by these findings, from one of the largest human challenge studies performed to date, which pave the way for further development of this first-in-class vaccine," said Dr Rajeev Venkayya, executive vice president and head of Takeda's Vaccine Business Division. "The research and development of innovative vaccines like our norovirus candidate reflect Takeda's commitment to addressing the most important challenges in global public health."