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ASIA EDITION

Positive result for PaxVax's oral cholera vaccine

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Singapore: US-based PaxVax, a specialty vaccine company, has confirmed positive efficacy results from 90-day challenge studies of its single-dose oral cholera vaccine candidate, PXVX0200. This utilizes the same attenuated vaccine strain (CVD 103-HgR) previously approved and marketed in several countries under the brand name Orochol. Trial investigators compared the rate of diarrhea in participants vaccinated with PXVX0200 to the rate in participants who had received placebo.

Vaccine efficacy was evaluated by immunizing volunteer participants with an oral dose of the PXVX0200 vaccine or placebo and then subsequently exposing them to the cholera-causing agent (Vibrio cholerae O1 El Tor). Volunteer participants in this challenge study were divided into two groups, the first group was vaccinated and then challenged at 10 days after vaccination, and a second, separate group of volunteer participants was challenged at 90 days post vaccination to further evaluate duration of vaccine protection.

Study Investigator Dr Beth Kirkpatrick, Professor of Medicine, Infectious Disease Medicine, Department of Medicine, University of Vermont commented, "The 90-day challenge results are very encouraging and provide important new data that further support the efficacy of PXVX0200 in protecting people exposed to cholera. If approved, PXVX0200 has the potential to provide an effective new single-dose option for people living in and travelling to areas where cholera is endemic."

In addition to the 10 and 90 day cholera challenge studies, immunogenicity, safety, and lot-to-lot consistency of the PXVX0200 cholera vaccine are being evaluated in a broader population at study sites in Australia, Canada, and the U.S. Approximately 3,000 participants are being enrolled in these additional pivotal Phase 3 clinical studies.

"These favorable data build on a successful 10-day challenge study and provide important new data to support a Biologics License Application for PXVX0200, our lead commercial vaccine candidate," said Kenneth Kelley, chief executive officer, PaxVax. "US travelers currently have limited options to protect themselves from cholera, and we are pleased with the progress we are making in bringing an effective and logistically simple, single-dose cholera vaccine to travelers as well as developing countries for use during fast-moving cholera outbreaks."

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Cholera is an acute intestinal diarrheal infection caused by toxigenic Vibrio cholerae bacteria generally acquired by ingesting contaminated water or food. According to the World Health Organization, the global disease burden is estimated to be three to five million cases and 100,000 to 130,000 deaths per year. Cholera often manifests as explosive epidemics that rapidly move through populations, such as the outbreaks that occurred in Peru and Haiti in 1991 and 2010, respectively.

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