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Safety and immunogenicity of live oral cholera vaccine CVD 103-HgR (Vaxchora) in children and adolescents (2-17 years)

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Background: The attenuated recombinant Vibrio cholerae O1 strain CVD 103-HgR (Vaxchora®), elicits a rapid serum vibriocidal antibody (SVA) response and protects against cholera-induced diarrhea in adult volunteer challenge trials but has not been studied in children/adolescents.

Methods: A phase 4, placebo-controlled, double-blind, multi-center study was performed to assess safety, immunogenicity, and tolerability of a single oral dose of Vaxchora vaccine in children and adolescents . Volunteers in 3 cohorts (ages 12-17, 6-11, 2-5 years) were randomized 6:1 to receive 1 x 109 colony forming units of vaccine or placebo. Immunogenicity endpoints included SVA seroconversion rates, GMTs, and GMFI on days 1, 11, 29 (ages 2-17), and 91, 181 (ages 12-17), and days 365, 547, and 730 in a subset of the 12-17 year-old cohort. Safety was assessed by comparing solicited signs and symptoms on days 1-8, unsolicited adverse events through day 29, and serious adverse events through day 181.

Results: The SVA seroconversion rates 10 days after immunization were 99.4%, 97.8%, and 98.1% in the ages 12-17, 6-11, and 2 -5 year cohorts, respectively, and were non-inferior to the 98.3% rate in a bridging population of adults 18-45 years. In adolescents, GMTs and GMFI remained elevated above baseline through day 181, and SVA seroconversion persisted for 2 years after vaccination in the 12-17 years cohort. Most reactogenicity was mild to moderate; rates were similar in vaccine and placebo recipients. There were no vaccine related SAEs.

Conclusion: Vaxchora vaccine appears to be safe, immunogenic, and well tolerated in children and adolescents.