Efficacy and safety of a rotavirus vaccine

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Prevention of rotavirus disease through vaccination is a public health priority. In 2009, the World Health Organization recommended rotavirus vaccination be introduced in all countries to reduce disease burden and mortality among young children.

Two live oral attenuated rotavirus vaccines are globally licensed and WHO prequalified for the prevention of rotavirus gastroenteritis. Safety and efficacy of these vaccines has been established in high- and middle-income countries, but vaccination in sub-Saharan Africa, where there is the largest burden of rotavirus-related mortality, presents certain logistical and financial challenges.

BRV-PV is a low-cost and heat-stable rotavirus vaccine manufactured by the Serum Institute of India, Limited whose introduction may help minimize the burden on already-strained national immunization programs throughout sub-Saharan Africa.

We conducted a double-blind, placebo-controlled randomized phase III event-driven trial in Niger to assess the efficacy and safety of BRV-PV against severe rotavirus gastroenteritis in infants in Niger. Infants were randomized in a 1:1 ratio to receive three doses of BRV-PRV or placebo at approximately 6, 10, and 14 weeks of age.

Cases of gastroenteritis and adverse events were captured through facility and home-based surveillance from 28 days post Dose 3 (gastroenteritis) and from the moment the first dose until 2 years of age. As an event-driven trial, the primary efficacy analysis is planned when 117 cases of severe rotavirus gastroenteritis. Vaccine efficacy against severe rotavirus gastroenteritis and risk of serious adverse events, including hospitalization, intussusception and death will be presented.

Evidence supporting the efficacy and safety of BRV-PV vaccine in an African setting would support the pre-qualification of and increased access to rotavirus vaccine across Africa.

Results of a phase III trial on the efficacy and safety of a low-cost, heat-stable oral rotavirus vaccine against severe rotavirus gastroenteritis are presented. Efficacy and safety results are presented.