Non-inferiority (NI) Study of Purified Vero Rabies Vaccine-Serum Free (VRVg-2) in 3-dose and 2-dose Pre-exposure Prophylaxis (PrEP) Regimen in Comparison with Licensed Rabies Vaccines

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Background

A serum-free, highly purified rabies vaccine (VRVg-2) is under development as improvement to licensed vaccines: Imovax Rabies and Verorab.

Methods

Phase III, multi-center, randomized, controlled trial (NCT04127786) which enrolled 505 pediatric (1 to <18years) and 505 adult (≥18years) participants vaccinated intramuscularly with 3-dose PrEP regimen at Day(D)0, D7, D28 (Primary Series (PS) Cohort 1); and 698 adults with 2-dose PrEP regimen at D0, D7 (PS Cohort 2) using VRVg-2, Verorab or Imovax Rabies. Rabies virus neutralizing antibody (RVNA) titers were measured using rapid fluorescent focus inhibition test at D28 post-dose (PD) 2 in both cohorts and D42 (PD3) in cohort 1. Safety data were collected. NI was tested based on margin -5% using two-sided 95% confidence interval of the difference of proportions of participants reaching RVNA titers≥0.5IU/mL between VRVg-2 groups and comparators.

Results

NI of 3-dose VRVg-2 versus 3-dose licensed vaccines at D42 (PS cohort 1) was demonstrated in both pediatric (vs. Verorab: -1.4%; vs. Imovax Rabies: -1.4%) and adults (vs. Verorab: -0.6%; vs. Imovax Rabies: -1.5%). NI of 2-dose VRVg-2 vs. 2-dose licensed vaccines at D28 (pooled PS cohorts 1 and 2) was also demonstrated in pediatric (vs. Verorab: -1.4%; vs. Imovax Rabies: -1.4%) and adults (vs. Verorab: -1.9%; vs. Imovax Rabies: -0.5%).

Similar rates of solicited reactions and unsolicited adverse events were reported among 3 groups in each cohort.

Conclusion

Data support the use of VRVg-2 in 2-dose and 3-dose PrEP with safety profile comparable to licensed vaccines.