Benefit risk assessment for a next generation Purified Vero Rabies Vaccine-Serum Free (PVRV-NG2) in pre- and post-exposure prophylaxis

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BACKGROUND

We present the structured benefit-risk assessment supporting the marketing authorization application for PVRV-NG2, a next-generation rabies vaccine using state-of-the-art manufacturing process designed to enhance supply sustainability.

MATERIALS AND METHODS:

A structured approach was applied to evaluate the benefit-risk profile of PVRV-NG2 in pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP) regimens, including a semi-quantitative analysis (SQA). The SQA utilized data from four Phase 3 studies (approximately 2900 participants) comparing PVRV-NG2 with approved rabies vaccines (Purified Vero-cell Rabies Vaccine [PVRV] and Human Diploid Cell Vaccine [HDCV]), across common PrEP and PEP regimens, age groups and administration routes. Benefit outcome measures included immune response (rabies virus neutralizing antibody titer ≥ 0.5 IU/mL) at regimen-specific timepoints. Risk outcome measures included rates of Grade 3 solicited reactions within 7 days post-vaccination, serious adverse events (SAEs) and adverse events of special interest (AESIs) within 28 days and up to 6 months after last vaccination.

RESULTS:

The SQA presents forest plots of rate differences and 95% confidence intervals comparing PVRV-NG2 with comparators for immunogenicity benefit and risk outcome measures. Across all studies, age groups, and regimens, no differences were observed in immune responses between PVRV-NG2 and comparators. Risk outcomes were generally comparable between vaccines in both adult and pediatric participants. No SAEs related to PVRV-NG2 and no AESIs were reported.

CONCLUSION:

PVRV-NG2 demonstrated a favorable benefit-risk profile across PrEP and PEP regimens and all age groups, with immunogenicity and safety consistent with current standard of care, while offering improved supply sustainability.