77.56% at 28th day and has a decrease of 5% after 6 months, whereas the sero-protection of the RS.JEV (Chinese vaccine, SA 14-14-2) is of this vaccine was studied in endemic and non-endemic areas. The efficacy cine was established in a Phase-I study on healthy adult volunteers and the results further confirmed in phase II/III study. The efficacy with encephalitis. The risk is highest in children aged 1-15 years, in rural areas and in the monsoon/post monsoon season.

JE vaccine (JENVAC®) development is a collaborative project between Bharat Biotech International Ltd, Hyderabad, India and National Institute of Virology, Pune, India.

Methods & Materials: Virus strain (821564-XY) used in vaccine development which is isolated from the endemic region of Kolar, Karnataka, India. The world’s first fully-integrated, single use bioreactor used for the production of JE vaccine using Vero cell line. Purification is performed using chromatography techniques. Formulation has been carried out with alluminium hydroxide gel.

Results: Non-clinical toxicology studies were conducted in lab animals and the vaccine has no toxic effects. The safety of this vaccine was established in a Phase-I study on healthy adult volunteers and the results further confirmed in phase II/III study. The efficacy of this vaccine was studied in endemic and non-endemic areas. The sero-protection of the RSJEV (Chinese vaccine, SA 14-14-2) is 77.56% at 28th day and has a decrease of 5% after 6 months, whereas JENVAC® showing sero-protection of 98.67% at 28th day of single dose vaccination and 99.78% after 56 days with a second dose vacci-nation. The Immunogenicity study has given 91% at 12 months, 67% at 18 months, 61% sero-protection even after 24 months.

Conclusion: The other vaccines available against JE virus are live attenuated which is derived from the primary hamster kidney cell culture whereas vaccine JENVAC® manufactured by Bharat Biotech is the first VERO cell derived inactivated indigenous vaccine which induces high immunity against JE virus in adults and children above one year and JENVAC® is found stable for 2 years at 2-8°C is commercially available. Based on the results it is concluded that JENVAC® gives long-term protection against Japanese encephalitis infection.

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Background: Japanese Encephalitis (JE) is a mosquito-borne disease caused by JE virus belongs to the family Flaviviridae. In Asia approximately 68,000 clinical cases among 10,000 deaths occurs every year. Although symptomatic JE is rare, the case-fatality rate among those with encephalitis can be as high as 30%. Permanent neurologic or psychiatric sequelae can occur in 30%–50% of those with encephalitis. The risk is highest in children aged 1-15 years, in rural areas and in the monsoon/post monsoon season.

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Results: Non-clinical toxicology studies were conducted in lab animals and the vaccine has no toxic effects. The safety of this vaccine was established in a Phase-I study on healthy adult volunteers and the results further confirmed in phase II/III study. The efficacy of this vaccine was studied in endemic and non-endemic areas. The sero-protection of the RSJEV (Chinese vaccine, SA 14-14-2) is 77.56% at 28th day and has a decrease of 5% after 6 months, whereas JENVAC® showing sero-protection of 98.67% at 28th day of single dose vaccination and 99.78% after 56 days with a second dose vaccination. The Immunogenicity study has given 91% at 12 months, 67% at 18 months, 61% sero-protection even after 24 months.

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