

## JEEV- Infusing life into humanity

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In 2005, Uttar Pradesh and neighboring Nepal witnessed death of over 1200 children during an epidemic outbreak of Japanese Encephalitis (JE), a deadly infectious disease found mainly in Asia. This deadly viral disease is the leading cause of Acute Encephalitis Syndrome (AES). The situation continues to remain the same even today. There were more than 8,000 confirmed cases recorded in India in 2011 with over 1100 death cases. JE is known for high mortality (upto 35-40 percent) and high morbidity, where upto 50 percent of all survivors end up with physical and mental disabilities after surviving the disease. There is no specific treatment available for JE and vaccination is the most effective weapon against the disease. Inactivated vaccines are considered to have a better safety profile as compared to live vaccines. Currently, there is no other vaccine available to private doctors in India.

Since there was no life saving vaccine available in the market for such a deadly viral disease, Biological E, one of the leading Indian vaccine manufacturers based at Hyderabad and having served the community for close to five decades decided to work in this area. Biological E started exploring for suitable technology to reduce the product development timelines and as the outcome in 2005, it signed a technology partnership agreement with the Austrian vaccine and biotechnology company, Intercell AG for the development, manufacturing, marketing and distribution of JE vaccine in India and in the Indian subcontinent.

Intercell AG has a technology whose base includes novel platforms, such as the patch-based delivery system and the proprietary human monoclonal antibody discovery system eMAB, in addition to well-established technologies upon which the company has entered into strategic partnerships with a number of leading pharmaceutical companies, including GSK, Merck, Novartis and Sanofi.

Using this technology Biological E has developed a vaccine against JE after seven years of in house R&D effort and support from its technology partner, Intercell AG. This vaccine is a second generation inactivated Japanese Encephalitis vaccine based on the SA 14-14-2 strain and does not contain any gelatin stabilizers or thimerosal and the vaccine's safety and efficacy has been established through multiple studies on Indian subjects and is also licensed by the Drug Controller General of India.

Biological E launched its inactivated Japanese Encephalitis vaccine marketed under the brand name "JEEV", in the domestic private market at price of Rs985 per 0.5ml vial. The vaccine is approved for immunization against JE for both pediatric and adult subjects.

Intercell's vaccine against Japanese encephalitis, which formed the basis for the technology transfer to Biological E, is licensed by the United States Food and Drug Administration, European Medicine Agency and multiple countries like Australia, Canada, and Switzerland.

"The availability of a safe and effective vaccine against JE is indeed good news for families and pediatricians in all JE endemic states of India. Very much like polio, JE is also a low frequency but high impact disease. When 200 children get infected with poliovirus, one gets polio; when 300 children get infected with JE virus, one gets encephalitis. Polio paralyzes but JE kills and causes brain damage in those who survive. Vaccine will enable families to take responsibility to protect their children. I congratulate Biological E for launching a high quality vaccine in India," said Dr T Jacob John, India's eminent pediatrician and virologist who presided over the product launch on September 13, 2012.

"With the launch of JEEV, the indigenous vaccine with excellent safety profile and proven efficacy in Indian subjects is now available to doctors for prevention of Japanese Encephalitis in children and adults," said Dr Vijay Kumar Datla, chairman and managing director of Biological E.

The chief executive officer of Intercell AG, Mr Thomas Lingelbach said, "Our strategic partnership with Biological E has supported us in taking a major step forward in achieving our goal of rolling-out this JE vaccine in endemic countries with a high medical need in order to protect children and adults against this terrible disease. Now, we will continue to fight against this disease and collaborate on increasing market penetration in the endemic region."

There is no other JE vaccine currently in the private market and JEEV is the only vaccine available. The Government of India imports a live attenuated vaccine from China for public immunization. JEEV is a second generation inactivated cell culture vaccine against JE.

Considering the need and gap in the market, Biological E is focusing on its sales efforts of JEEV initially on private market customers including pediatricians and general practitioners. To ensure a successful product launch, Biological E has recruited and trained its own sales force, which will initially be fully dedicated to the product. The company plans to offer the vaccine as a safer and indigenous alternative to the government for JE campaigns.

Biological E has also submitted the data for JEEV as part of the WHO prequalification process and will aim for export markets on completion of the WHO prequalification process for JEEV. The approval will enable the vaccine to be exported to global agencies. Meanwhile, many developing countries are showing their interest in its JE vaccine.