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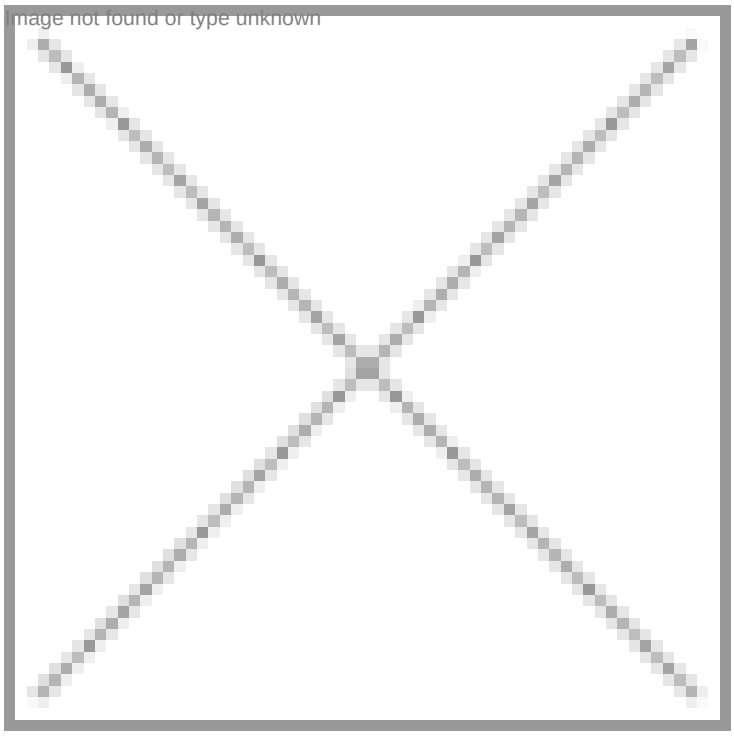

Rabirix to tackle rabies in India

With the launch of Rabirix by Bharat Biotech, the acute shortage of rabies vaccine may soon be history

Currently, the severe shortage of anti-rabies vaccine in the country results in nearly 80 deaths per day. The scenario should hopefully improve with the recent launch of a vero cell-based rabies vaccine-Rabirix by Bharat Biotech International Ltd (BBIL).

Indigenously developed by BBIL, the vaccine is indicated for both prophylactic (pre-bite) and therapeutic (post-bite) treatments. Rabirix is a lyophilized vero cell-based rabies vaccine (PVRV), which is chromatographically purified to reduce cellular DNA content and foreign protein content. The vaccine has proven to be well tolerated with minimal or no side effects.

Sharing details about project, Dr Krishna Ella, CMD, Bharat Biotech, said, "Presently, the rate of deaths occurring due to rabies is very high and these include a large number of children under the age of 15 years. Unfortunately most of these incidences are taking place in the urban slums or rural areas. Seeing their magnitude, I realized that the supply of the rabies vaccine is still a big problem in the country and decided to take the challenge head on."

The problem with rabies is that there is no chemical drug to treat or save the patients unlike other diseases; hence death is certain without a vaccine. It is an acute viral encephalitis transmitted from an infected animal to human by exposure to saliva. Human infection with rabies is nearly always secondary to animal bite, with dog being the major reservoir for human rabies.

Once clinical symptoms have occurred, the disease is almost invariably fatal.

The project was launched four years back with an investment of Rs 27 crore. "For developing a vaccine, we first needed a good validated virus strain, and that is where the Centre for Disease Control (CDC) came to our help and assisted us in getting the required strain," informed Ella. The virus strain for developing the vaccine was obtained from the CDC in Atlanta, USA.

Secondly, the company did not want to use roller bottles or an egg-based vaccine development strategy. Instead they decided to use a cell culture based approach. "The making of this vaccine has been an innovative process development exercise. There were many challenges, for instance, going for a cell culture based innovative formulation, stabilizing the protein, etc." The required vero cells, confirming to the necessary US FDA standards, for the vaccine development were procured from a US-based company.

Post the vaccine formulation, the clinical trials were conducted. The immune sera samples from Phase III clinical trials were analyzed for the vaccine's efficacy at the National Institute of Virology in Pune. The trials showed that Rabirix is at par with the existing vaccines available in the market.

Launching the vaccine at Hyderabad, Julie Gerberding, director, CDC Atlanta, said, "The development and commercialization of Rabirix in collaboration between the Centers for Disease Control and Prevention (CDC Atlanta) and Bharat Biotech is a great example of how public-private partnership entities in the US and India have joined forces to address public health concerns of the developing world."

Currently, four million people are exposed to the rabies virus worldwide every year and 60,000 people fall victim to it. In India three million people undergo anti-rabies treatment and 30,000 deaths are reported annually, which accounts for 50 percent of mortality from rabies worldwide.

"We have tried to look more from a social angle; our aim is to ensure that not a single child dies due to rabies in India." According to Ella, Rabirix would be 30 percent cheaper compared to the existing vaccines in India and the company is planning to adopt two different price strategies for the private and government sector. Currently imported vaccines dominate the market and their prices range between Rs 360 and Rs 380 per dose. At present, poor people cannot afford to buy vaccines, which cost around Rs 1,500 ($32) for a full course from private hospitals and chemists.

The domestic market size for anti-rabies vaccine is estimated to be Rs 400 crore, while the export market is about Rs 1,500 crore. Although the vaccine has great export potential, Ella stressed that they would first look at the Indian requirement and demand. "Initially the focus of the vaccine will be on India, especially on the rural healthcare system. We need an innovative distribution mechanism to reach the masses," he said.

Rolly Dureha