

India announces low-cost rotavirus vaccine (Update)

May 14 2013, by Ravi Nessman

The Indian government announced Tuesday the development of a new low-cost vaccine proven effective against a diarrhea-causing virus that is one of the leading causes of childhood deaths across the developing world.

The Indian manufacturer of the new rotavirus vaccine pledged to sell it for \$1 a dose, a significant discount from the cost of the current vaccines on the market. That reduced price would make it far easier for poor countries to vaccinate their children against the deadly virus, health experts said.

Rotavirus, spread through contaminated hands and surfaces, kills about half a million children across the world each year, 100,000 of them in India.

At a conference Tuesday, the government announced that Phase III trials of Rotavac proved that it was safe as well as effective. The clinical trial of 6,799 infants at three sites in India showed the vaccine reduced severe cases of diarrhea caused by rotavirus by 56 percent during the first year of life.

"The clinical results indicate that the vaccine, if licensed, could save the lives of thousands of children each year in India," said Dr. K. Vijay Raghavan, the secretary of the Department of Biotechnology.

The vaccine still needs to be licensed before it can be distributed in India

and would require further approval by the World Health Organization before it could be distributed globally.

Two other vaccines have proven effective against rotavirus, but they are significantly more expensive.

The GAVI Alliance, which works to deliver vaccines to the world's poor, negotiated a significant discount last year with GlaxoSmithKline and Merck, obtaining the rotavirus vaccines from those pharmaceutical companies for \$2.50 a dose. The alliance has programs for delivering those vaccines in 14 countries and plans to expand them to 30 countries.

Dr. Seth Berkley, the GAVI Alliance's CEO, said the announcement Tuesday was "a big deal."

"The cheaper the price the more children you can immunize," he said, adding that it will still take some time before the vaccine is approved for use.

In addition, having a third manufacturer for the vaccines would ease supply shortages and could drive down the costs charged by the other manufacturers, he said.

"That would make a big difference in terms of changing the marketplace," he said.

Diarrhea is the second leading cause of death among young children in the world after pneumonia. A study of 22,568 children at sites in seven African and south Asian countries that was published Monday in the medical journal The Lancet showed that rotavirus was the leading cause of moderate to severe diarrhea in children under the age of two.

The new vaccine was developed from a weakened strain of the virus

taken from a child hospitalized in New Delhi more than a quarter century ago. It was the result of a broad global partnership that included the government, the Indian company Bharat Biotech, the Bill and Melinda Gates Foundation and the U.S. Centers for Disease Control and Prevention, among many others.

Those involved said the broad cooperation reduced research costs for the manufacturer and helped keep the vaccine inexpensive.

"This public-private partnership is an exemplary model of how to develop affordable technologies to save lives," Bill Gates, co-chair of the Gates Foundation, said in a statement.

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