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## **MEXICAN AUTHORITIES APPROVE NEW ROTAVIRUS VACCINE, ROTARIX™ TO PREVENT ROTAVIRUS GASTROENTERITIS IN INFANTS**

GlaxoSmithKline (GSK) announced today that on July 12<sup>th</sup> 2004, the Board of Health in Mexico approved for marketing in Mexico a new vaccine, Rotarix™, for the prevention of gastroenteritis caused by rotavirus infection.

Rotavirus infection is the leading cause of severe diarrhoea and vomiting in infants and young children between 3-24 months world-wide. If untreated, the virus can rapidly kill, as the sickest children become dehydrated from 10 to 20 episodes of diarrhoea in a single day. Globally, rotaviruses account for approximately 138 million cases of infantile gastroenteritis each year and it was recently reported that rotavirus is responsible for approximately 440,000 deaths per year - a child a minute - the majority of which occur in the Indian subcontinent, sub-Saharan Africa and South America.

Rotarix is an oral, two-dose, live attenuated vaccine developed from a single human strain designed to provide broad protection against multiple rotavirus strains and to provide early protection before the onset of rotavirus illness. The vaccine works by stimulating the body to mimic the immune response to natural rotavirus infection, which protects against the subsequent development of moderate to severe rotavirus disease.

More than 70,000 infants have been enrolled in the global clinical development program, with studies conducted in Europe, the US, Latin America and Asia to evaluate the safety and efficacy of Rotarix. These studies demonstrate that Rotarix is an effective, safe and well-tolerated vaccine.

Rotarix has been designed to fit in with a country's existing infant vaccination schedules with both doses given before 6 months of age.

Rotarix has shown up to 90% efficacy against severe rotavirus-related gastro-enteritis in the first year of life, as defined by the well established and widely used Vesikari 20-point scale, and up to 84% efficacy in the second year of life against severe rotavirus-related gastro-enteritis. In addition, Rotarix was 86% effective in preventing hospitalisations due to rotavirus-related gastro-enteritis. Rotarix has demonstrated protection against different circulating strains of rotavirus when compared to the original strain of the vaccine.

Rotarix has demonstrated a side effect profile similar to that of a placebo vaccine with only limited reactogenicity observed. To date, there is no evidence of an increased risk of intussusception. An Independent Data Safety Monitoring Board (IDSMB), which monitors the safety aspects of the Rotarix clinical development program, has reviewed the data on an ongoing basis.

‘We are delighted that Mexico has become the first country in the world to approve Rotarix, an important new vaccine to prevent severe rotavirus-related gastro-enteritis in infants worldwide’ said Jean Stéphenne, President and General Manager of GSK Biologicals.

Rotarix has been in development at GSK Biologicals since 1997 when it was in-licensed from AVANT Immunotherapeutics.

## **NOTES FOR EDITORS**

### **ROTAVIRUS INFECTION**

Rotavirus, an intestinal infection, is the leading cause of severe diarrhoea and vomiting (gastroenteritis) in infants and young children between 3-24 months world-wide. If untreated, the virus can rapidly kill, as the sickest children become dehydrated from 10 to 20 episodes of diarrhoea in a single day<sup>2-4</sup>. The infection is usually transmitted by the faecal-oral route and is highly contagious. Improved hygiene does not prevent transmission of rotavirus.

This virus is responsible for approximately 440,000 deaths per year (equivalent to a child a minute), the majority of which occur in the Indian subcontinent, sub-Saharan Africa and South America<sup>4</sup>. Recent data presented at the 6<sup>th</sup> International Rotavirus Symposium in Mexico City, indicate that the annual number of deaths due to rotavirus infection may be as high as 608,000 deaths per year (39 percent of the 1.56 million deaths from all diarrhoea worldwide)<sup>5</sup>. Globally, rotaviruses account for approximately 138 million cases of infantile gastroenteritis each year and an estimated 1,205 children die from rotavirus disease every day—equivalent to approximately one child a minute—mainly in countries of the developing world.<sup>4</sup>

Virtually all children, by the time they have reached 2 to 5 years of age, will have been exposed to human rotavirus circulating naturally in the environment<sup>2-4</sup>. Hospitalisations due to rotavirus gastro-enteritis are substantial in high-income countries and usually peak in the winter months.

About the vaccine **Rotarix**

Rotarix™ is a new rotavirus vaccine from GlaxoSmithKline and represents a novel approach to rotavirus vaccine development. Rotarix has been in development at GSK Biologicals since 1997 when it was in-licensed from AVANT Immunotherapeutics.

Clinical studies have been conducted in Europe, the US, Latin America and Asia and demonstrate that Rotarix is effective, safe and a well-tolerated vaccine.

Rotarix is a live vaccine based on a single attenuated human rotavirus strain (G1) - the rationale is to mimic natural infection caused by the wild-type virus without causing disease (gastroenteritis). Rotarix offers protection against rotavirus gastroenteritis because it delivers broad protection when it is needed (before the highest incidence of disease occurs).

In the studies conducted, Rotarix has an efficacy of 63-73% protection against any rotavirus diarrhea and between 78 to 90% against severe rotavirus diarrhea over the first rotavirus epidemic season, and 73% and 84% against any and severe rotavirus diarrhea respectively over two consecutive seasons. Protective efficacy in preventing hospitalisations due to rotavirus-related gastro-enteritis was 86% for Rotarix.

Severe gastro-enteritis was defined on the established and widely used Vesikari 20-point scale which evaluates the full clinical picture of rotavirus related gastro-enteritis by taking into account the severity and duration of the diarrhea and vomiting, the severity of fever and dehydration as well as the need for treatment<sup>6</sup>.

Importantly, Rotarix offers protection in a setting where multiple serotypes circulate (both G1 and non-G1 (including G9)<sup>7-8</sup>. Rotarix efficacy against severe rotavirus-related gastro-enteritis caused by non-G1 strains was 74%.

It has demonstrated side effect profile similar to that of a placebo vaccine with only limited reactogenicity observed. To date, there is no evidence of an increased risk of intussusception.

Rotarix is given in the first 6 months of life, with the first dose between 6 and 14 weeks of age, followed by a second dose between 14 and 24 weeks of age with a minimum interval of 4 weeks between the two doses.

GSK plans to conduct exhaustive post-marketing surveillance in collaboration with the appropriate authorities.

## REFERENCES

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## GLAXOSMITHKLINE BIOLOGICALS

GlaxoSmithKline Biologicals (GSK Biologicals), one of the world's leading vaccine manufacturers, is located in Rixensart, Belgium, which is the centre of all GlaxoSmithKline's activities in the field of vaccine research, development and production. GSK Biologicals employs more than 1000 research scientists, who are devoted to discovering new vaccines and developing more cost-effective and convenient combination products to prevent infections that cause serious medical problems worldwide.

In 2003, GSK Biologicals distributed more than 850 million doses of vaccines to 152 countries in both the developed and the developing world – an average of 27 doses per second. Of those vaccine doses, approximately 85 million were doses of combination paediatric vaccines, which protect the world's children against a minimum of three – and as many as six – diseases in one vaccine. For more information, visit GlaxoSmithKline's vaccine websites at [www.gsk-bio.com](http://www.gsk-bio.com) and [www.worldwidevaccines.com](http://www.worldwidevaccines.com) (for medical professionals).

GlaxoSmithKline – one of the world's leading research-based pharmaceutical and healthcare companies – is committed to improving the quality of human life by enabling people to do more, feel better and live longer.

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