

**FOR IMMEDIATE RELEASE**

**MERCK'S INVESTIGATIONAL ROTAVIRUS VACCINE EFFECTIVELY  
PROTECTS INFANTS AGAINST SEVERE ROTAVIRUS DISEASE**

**The New England Journal of Medicine publishes Phase III data from one of the largest vaccine trials ever on the prevention of a major cause of infant vomiting and diarrhea**

**MONTREAL, Quebec – January 5, 2006** – Merck & Co's investigational oral vaccine is 98 per cent effective in preventing severe forms of rotavirus infection, the most common cause of severe, dehydrating vomiting and diarrhea in infants, according to the results of the Rotavirus Efficacy and Safety Trial (REST), published today in *The New England Journal of Medicine*. The Merck investigational oral pentavalent vaccine contains five rotavirus strains (G1, G2, G3, G4 and P[8]). The G1, G2, G3 and G4 strains are responsible for approximately 95 per cent of rotavirus disease in Canada.<sup>1</sup>

“Rotavirus is an unpredictable disease, which can become severe very rapidly. It can be extremely frightening for parents to see their young children get so sick, so fast,” said Dr. John Yaremko, a practicing paediatrician and Assistant Professor of Paediatrics at McGill University. “Results from REST are substantial because they show it is possible to prevent rotavirus gastroenteritis without the worry of any significant side effects compared to placebo, which is so important when infants are involved.”

Virtually all children (95 per cent) are infected with rotavirus at least once by the age of five.<sup>2</sup> Equally prevalent in the developed and developing world, rotavirus is highly contagious and does not discriminate – none of social class, hygienic measures or good nutrition appear to affect its prevention. Rotavirus infection usually starts with fever, abdominal pain and vomiting, followed by diarrhea. These symptoms can be mild to severe and generally last for three to nine days with up to 20 episodes of diarrhea a day.<sup>3,4</sup> Severe cases can lead to rapid dehydration, which could result in death if untreated.<sup>5</sup>

In Canada, rotavirus is the most important cause of severe gastroenteritis hospitalizing infants between six and 35 months.<sup>6,7</sup> It is estimated to cause up to 7,400 hospitalizations, 26,000 ER visits and 54,000 physician visits per year, with a cost to the Canadian health care system of up to \$31 million. The total annual economic burden adds up to \$69 million when parental out of pocket expenses and work loss are included.<sup>8</sup>

“I was shocked when my daughter became infected with rotavirus two years ago. She got dehydrated so quickly because of the severe vomiting and diarrhea and she couldn’t keep down any liquids for several days,” said Vancouver parent Pamela Lloyd, whose daughter Emily was infected with rotavirus at two years old. “It was scary. I wouldn’t wish this on any child or parent.”

### **One of the largest vaccine trials ever**

REST is a double-blind, randomized, placebo-controlled study. It is one of the largest vaccine trials ever, with nearly 70,000 infants aged six to 12 weeks at enrolment from 11 countries: US, Finland, Sweden, Germany, Belgium, Italy, Mexico, Guatemala, Costa Rica, Jamaica and Taiwan. Merck designed this study to be large enough to provide a meaningful evaluation of efficacy and safety of its vaccine with respect to intussusception. Intussusception is a condition that can damage the intestine and that is associated with the use of a vaccine made by another manufacturer and previously licensed in the US. REST results showed that the incidence of intussusception was the same in both the vaccine and the placebo groups.

### **Significantly reduced ER visits, hospitalizations and physician visits**

The REST results demonstrated that Merck’s investigational oral pentavalent vaccine reduced rotavirus-related emergency room visits by 94 per cent, hospitalizations by 96 per cent and visits to the doctor by 86 per cent compared to placebo. The data also showed:

- Efficacy in preventing 98 per cent of severe rotavirus diseases caused by the most prevalent serotypes worldwide (G1, G2, G3, G4 and P[8]) and 74 per cent efficacy against all cases combined regardless of severity;
- No clinically significant increase in fever, vomiting, diarrhea or bloody stools compared to placebo.

### **About Merck Frosst**

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**References**

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**FOR INTERVIEWS with medical expert and patient, please contact Roch Landriault at 514-843-2345.**

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