

# **FOR IMMEDIATE RELEASE**

## ROTATEQ™ IS APPROVED IN CANADA

# THE FIRST AND ONLY VACCINE IN CANADA TO PREVENT ROTAVIRUS GASTROENTERITIS IN INFANTS

MONTREAL, Quebec – August 23, 2006 – Parents will now be able to protect their infants against a potentially severe virus as Merck Frosst Canada Ltd. announced that Health Canada has approved RotaTeq<sup>™</sup>, the first and only vaccine available in Canada for use in preventing rotavirus gastroenteritis (serotypes G1, G2, G3, G4 and P1[8]) in infants. RotaTeq<sup>™</sup> is an oral, three dose vaccine given to infants between the ages of six to 32 weeks.

"This is exciting news for parents and the medical community," said Dr. John Yaremko, a practicing paediatrician and Assistant Professor of Paediatrics at McGill University. "Rotavirus is a highly contagious virus that infects more than 95 per cent of children at least once by the age of five. This new vaccine provides a broad protection against a disease whose symptoms can be severe and unpredictable."

Rotavirus is the most common cause of severe gastroenteritis – an inflammation of the stomach and intestines – in infants and children between six and 35 months of age. 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 in some cases. Severe diarrhea and vomiting caused by rotavirus can lead to rapid dehydration, which can be life-threatening if untreated.

"My daughter had diarrhea and was vomiting so much that she wanted to sleep on the floor in the bathroom," said Pamela Lloyd, a Vancouver parent whose daughter Emily had rotavirus at two years old. "I didn't know what rotavirus was, kids always get sick when they are young but this was the scariest experience I've ever been through with her and I wouldn't wish this on any child or parent."

RotaTeq<sup>™</sup> is an oral, pentavalent vaccine that contains five rotavirus strains (G1, G2, G3, G4 and P1[8]) responsible for approximately 95 per cent of rotavirus disease in Canada.<sup>5</sup> The first dose of RotaTeq<sup>™</sup> should be administered at six to 12 weeks of age; the subsequent doses should be administered at an interval of four to 10 weeks between each dose. RotaTeq<sup>™</sup> can also be given during the current routine baby visits at two, four and six months. Administered orally, the vaccine is ready-to-use and each dose is supplied in a squeezable plastic, latex-free dosing tube with a twist-off cap thereby reducing children's discomfort by minimizing the number of injections they receive.

## Reduced ER visits and hospitalizations

In Canada, rotavirus is estimated to cause up to 7,000 hospitalizations, 27,000 ER visits and 56,000 physician visits per year, with a cost to the Canadian health system of \$17 million annually. The total annual economic burden adds up to \$46 million per year and parents miss an average of 1.6 days of work to care for their child for each rotavirus episode.<sup>6,7</sup>

"Soon we will be facing rotavirus season which leads to an increased number of visits to the emergency room for diarrhea and vomiting. It can be extremely frightening for parents to see their children get so sick, so fast," explains Dr. Janine Flanagan, a practising Toronto emergency room physician. "This new vaccine will help to protect children from a disease which is highly contagious and unpredictable. It will also lessen the burden on hospital resources."

Rotavirus infection is seasonal from November to June and peaks in April/May.<sup>1</sup> Equally prevalent in the developed and developing world, rotavirus is highly contagious and does not discriminate – none of the social class, hygienic measures or good nutrition appear to affect its prevention.<sup>8</sup>

# One of the largest vaccine trials ever

The clinical trial program for RotaTeq<sup>™</sup> was one of the largest ever for a vaccine. More than 70,000 infants aged six to 12 weeks were studied in 11 countries. The double-blind, randomized, placebo-controlled studies evaluating the efficacy of the vaccine showed that RotaTeq<sup>™</sup> prevented 74 per cent of all rotavirus gastroenteritis cases and 98 per cent of the severe cases. In addition RotaTeq<sup>™</sup> prevented 94 per cent of rotavirus-related emergency room visits and 96 per cent of hospitalizations due to rotavirus gastroenteritis.<sup>9</sup>

The clinical trial program for RotaTeq™ was designed to be large enough to provide a meaningful evaluation not only of its efficacy but also the vaccine's safety with respect to intussusception (a condition that can damage the intestine and that was associated with the use of a vaccine made by another manufacturer and previously licensed in the US). RotaTeq™ was not associated with an increased risk of intussusception when compared to placebo. In addition, it was not associated with an increased risk of other serious adverse events when compared to placebo.<sup>9</sup>

"With the approval of RotaTeq™, Merck Frosst continues its leadership role of developing vaccines that address important unmet medical needs," said Dr. Ernest Pregent, Director, Medical Services, Merck Frosst Canada Ltd. "Having seen parental concern for their child from the inside of an ER room, RotaTeq™ is an especially welcomed addition to our vaccine family."

RotaTeg<sup>™</sup> should be available this fall through Canadian physicians and pharmacists.

#### **About Merck Frosst**

At Merck Frosst, patients come first. Merck Frosst Canada Ltd. is a research-driven pharmaceutical company. Merck Frosst discovers, develops and markets a broad range of innovative medicines to improve human health. Merck Frosst is one of the top 20 R&D investors in Canada, with an investment of \$117 million in 2005. The Company is committed to fostering partnerships to deliver the most valuable health outcomes for Canadian patients. More information about Merck Frosst is available at <a href="http://www.merckfrosst.com">http://www.merckfrosst.com</a>.

## **Forward-Looking Statement**

This press release contains "forward-looking statements" as that term is defined in the Private Securities Litigation Reform Act of 1995. These statements are based on management's current expectations and involve risks and uncertainties, which may cause results to differ materially from those set forth in the statements. The forward-looking statements may include statements regarding product development, product potential or financial performance. No forward-looking statement can be guaranteed, and actual results may differ materially from those projected. Merck undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events, or otherwise. Forward-looking statements in this press release should be evaluated together with the many uncertainties that affect Merck's business, particularly those mentioned in the cautionary statements in Item 1 of Merck's Form 10-K for the year ended Dec. 31, 2005, and in its periodic reports on Form 10-Q and Form 8-K, which the Company incorporates by reference.

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**NOTE:** A b-roll will be distributed today via satellite from 10:30 to 11:30 EDT.

Coordinates: Anik F2C, Transponder 3B, Audio 6.2 and 6.8, Downlink frequency

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- <sup>7</sup> Sénécal M, Brisson M, Lebel MH et al. for the MIRAGE study group. Burden of rotavirus associated gastroenteritis in Canadian families: a prospective community based study. Presented at the 24<sup>4h</sup> Annual Meeting of the European Society for Paediatric Infectious Diseases, May 3-5, 2006, Basel, Switzerland: (poster).
- <sup>8</sup> http://www.medicinenet.com/rotavirus/article.htm, accessed December 2, 2005
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