



## News Release

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### **FDA APPROVES MERCK'S ROTATEQ<sup>®</sup>, THE ONLY VACCINE IN THE U.S. TO PREVENT ROTAVIRUS GASTROENTERITIS, A LEADING CAUSE OF SEVERE INFANT DIARRHEA**

#### **ROTATEQ Fits Into Routine Well-Baby Visit Schedule**

WHITEHOUSE STATION, N.J., Feb. 3, 2006 – Merck & Co., Inc. announced today that the U.S. Food and Drug Administration (FDA) approved ROTATEQ<sup>®</sup> (rotavirus vaccine, live, oral, pentavalent), the only vaccine available in the U.S. to prevent rotavirus gastroenteritis, a leading cause of severe diarrhea in infants and young children. ROTATEQ is an oral, three-dose vaccine given to infants between the ages of six to 32 weeks.

“Virtually all children will experience rotavirus. While some children experience mild symptoms of rotavirus, infection can be severe and lead to dehydration that can be fatal,” said Paul Offit, M.D., chief of infectious diseases, The Children’s Hospital of Philadelphia and co-inventor of the vaccine. “The FDA approval of this vaccine is exciting for pediatricians because they will now have a way to help protect infants from rotavirus. For the many people who have worked on the research and development of this vaccine for nearly 20 years, to see that effort result in the availability of a vaccine to prevent this common and unpredictable disease is something to be proud of.”

ROTATEQ can be given during the current routine well baby visits at two, four, and six months of age. It is ready-to-use without re-formulation or mixing and is the only oral vaccine approved for use in infants in the U. S. The Advisory Committee on Immunization Practices (ACIP) is expected to decide whether ROTATEQ should be added to the current pediatric immunization schedule of recommended vaccines later this month. ROTATEQ should not be used in infants that are allergic to any component of the vaccine.

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**ROTATEQ<sup>®</sup> is a registered trademark of Merck & Co., Inc.**

ROTATEQ is a pentavalent vaccine that targets the strains of rotavirus responsible for more than 90 percent of rotavirus disease in the U.S. Among children under five in the United States, it is estimated that 2.7 million episodes of rotavirus gastroenteritis occur each year, leading to approximately 250,000 emergency room (ER) visits and up to 70,000 hospitalizations. In the U.S., children are at the greatest risk for severe rotavirus disease from six to 24 months of age. By the time they are five years old, approximately one out of every 17 children in the U.S. will visit the emergency room, and one out of every 65 will be hospitalized for rotavirus gastroenteritis in the U.S. Published surveys show that many pediatricians and family physicians believe rotavirus gastroenteritis is a significant disease for children and that 94 percent of physicians would use a rotavirus vaccine.

### **ROTATEQ Prevented Rotavirus Disease with A Safety Profile Similar to Placebo**

The FDA approval of ROTATEQ is based on data from Merck's Phase III clinical trials of more than 70,000 infants, including the Rotavirus Efficacy and Safety Trial (REST), one of the largest pre-licensure vaccine clinical trials ever conducted.

Among infants observed in Phase III clinical trials, ROTATEQ prevented 98 percent of severe cases of rotavirus gastroenteritis and prevented 74 percent of rotavirus gastroenteritis cases of any severity caused by serotypes targeted by the vaccine (G1, G2, G3, G4) compared to placebo through the first full rotavirus season after vaccination. In REST, ROTATEQ reduced hospitalizations by 96 percent and ER visits by 94 percent for rotavirus gastroenteritis caused by serotypes targeted by the vaccine through the first two years after the third dose. As with any vaccine, vaccination with RotaTeq may not result in complete protection in all recipients.

Because intussusception was associated with a previously licensed rotavirus vaccine made by another manufacturer, one of the primary goals of REST was to evaluate the safety of ROTATEQ with respect to intussusception. Intussusception takes place when the bowel folds in on itself, causing an intestinal blockage. It is a naturally occurring event, which occurs in approximately one in two thousand infants under the age of two each year. In REST, ROTATEQ did not increase the risk of intussusception compared to placebo. Within one year after the first dose, there were 13 cases of intussusception in the vaccine group and 15 in the placebo group.

The incidence of serious adverse events within six weeks of a dose of ROTATEQ was comparable among vaccine and placebo recipients. The most frequently reported serious adverse events were bronchiolitis, gastroenteritis, pneumonia, pyrexia, and urinary tract infection.

## **Pricing and CPT Code for ROTATEQ**

ROTATEQ is available for ordering. The catalog price for ROTATEQ is \$62.50 per dose when purchased as a pack of 10 single-dose tubes. The American Medical Association has established a Current Procedural Terminology (CPT)<sup>®</sup> code of “90680”<sup>1</sup>. CPT codes allow for the identification and potential reimbursement of existing common procedures, services and products; new and emerging technologies, as well as the collection of data to facilitate performance measures.

## **Selected Important Information about ROTATEQ**

ROTATEQ is indicated for the prevention of rotavirus gastroenteritis in infants and children caused by the serotypes G1, G2, G3, and G4 when administered as a 3-dose series to infants between the ages of 6 to 32 weeks. The first dose of ROTATEQ should be administered between 6 and 12 weeks of age. The efficacy of ROTATEQ beyond the second season after vaccination was not evaluated. The safety and efficacy of ROTATEQ have not been established in infants less than six weeks of age or greater than 32 weeks of age. No safety or efficacy data are available for the administration of ROTATEQ to infants who are potentially immunocompromised, including: those with certain disorders of the bone marrow or lymphatic system, those on immunosuppressive therapy or with an immunodeficient condition, or those who have received blood products within six weeks of vaccination. In more than 11,000 infants in clinical trials, a Vaccination Report Card was used to report the presence of adverse events for 42 days after each dose. Fever was observed at similar rates in vaccine and placebo recipients. Adverse events that occurred at a statistically higher incidence within six weeks of any dose among recipients of ROTATEQ as compared with placebo recipients were diarrhea, vomiting, otitis media (ear infection), nasopharyngitis (inflammation of the nasal passages and the pharynx), and bronchospasm.

## **Worldwide Availability of ROTATEQ Remains a Priority**

In addition to filing for licensure in more than 50 countries in 2005, Merck recently announced a collaborative effort with PATH to conduct clinical studies of ROTATEQ in Africa and Asia. The trials are an important step in the process of making a rotavirus vaccine available in these regions.

“With the approval of ROTATEQ, Merck continues its tradition of developing vaccines that address important unmet medical needs,” said Mark Feinberg, M.D., Ph.D, vice president of policy, public health and medical affairs, Merck Vaccines. “Because of the high rotavirus

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<sup>1</sup> Current Procedural Terminology (CPT) © American Medical Association. All Right Reserved.

mortality rates seen in the developing world, we plan to initiate clinical trials of ROTATEQ in economically disadvantaged countries in Africa and Asia. Merck is firmly committed to working with our partners in the global public health community to make ROTATEQ available to infants and children worldwide as quickly as possible," Dr. Feinberg said.

### **Two Additional Merck Vaccines Under Review with FDA**

Merck has two other vaccines currently under review by the FDA. The FDA and other regulatory agencies around the world are reviewing applications for ZOSTAVAX<sup>®</sup>, Merck's investigational vaccine to prevent shingles and shingles-associated pain in adults, and GARDASIL<sup>®</sup>, Merck's investigational HPV and cervical cancer vaccine.

The ACIP currently recommends vaccines for use in children to prevent diphtheria, Haemophilus influenzae type b, hepatitis A, hepatitis B, influenza, measles, meningococcal disease, mumps, pertussis, pneumococcal disease, polio, rubella, tetanus and varicella. Merck makes vaccines to help protect against seven of these 14 diseases.

### **About Merck**

Merck & Co., Inc. is a global research-driven pharmaceutical company dedicated to putting patients first. Established in 1891, Merck currently discovers, develops, manufactures and markets vaccines and medicines to address unmet medical needs. The Company devotes extensive efforts to increase access to medicines through far-reaching programs that not only donate Merck medicines but help deliver them to the people who need them. Merck also publishes unbiased health information as a not-for-profit service. For more information, visit [www.merck.com](http://www.merck.com).

### **Forward-Looking Statement**

This press release, including the financial information that follows, 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, 2004, and in its periodic reports on Form 10-Q and Form 8-K, which the Company incorporates by reference.

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**See attached prescribing information.**