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Merck Statement on Investigation of PCV Presented at Advisory Committee on Immunization Practices Meeting

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WHITEHOUSE STATION, N.J., October 28, 2010 - At today's U.S. Centers for Disease Control and Prevention's (CDC's) Advisory Committee on Immunization Practices (ACIP) meeting, Merck provided an update of its investigation and analysis of porcine circovirus 1 (PCV1) DNA fragments and porcine circovirus 2 (PCV2) DNA fragments in ROTATEQ® (Rotavirus Vaccine, Live, Oral, Pentavalent). In Merck's final test results, infectious PCV was not detected in ROTATEQ or in the starting materials used to make ROTATEQ. In addition, PCV1 DNA fragments were below the limit of detection, and PCV2 DNA fragments -- pieces of PCV2 and not the intact virus itself -- were at low levels in ROTATEQ.

In Merck's investigation, trypsin, the only porcine-derived raw material directly used in the manufacture of ROTATEQ, was confirmed as the source of PCV2 DNA fragments in ROTATEQ. Trypsin is an enzyme used in the manufacturing process for cell growth and rotavirus production.

There is information on PCV DNA in the Description section of the United States Prescribing Information for ROTATEQ. Specifically, the language in the section is as follows: "In the manufacturing process for ROTATEQ, a porcine-derived material is used. DNA from porcine circoviruses (PCV) 1 and 2 has been detected in ROTATEQ. PCV-1 and PCV-2 are not known to cause disease in humans."

According to the U.S. Food and Drug Administration (FDA) and other regulatory agencies around the world, there is no evidence that PCV1 or PCV2 poses a safety risk in humans, and neither is known to cause infection or illness in humans.

Merck is committed to the following actions:

- Developing approaches to enhance screening and removal of PCV from ROTATEQ
- Working closely with the FDA, and regulatory agencies around the world to evaluate current and emerging analytical technologies to enhance product quality assurance.

We remain confident in the safety profile and quality of ROTATEQ. ROTATEQ was studied in one of the largest pre-licensure vaccine clinical trials ever conducted. The safety profile of the vaccine has been and continues to be extensively evaluated by the FDA, the CDC, other regulatory agencies worldwide, and Merck.

As of June 2010, an estimated 37 million doses of ROTATEQ have been distributed worldwide. In the U.S., ROTATEQ is indicated for the prevention of rotavirus gastroenteritis in infants and children caused by serotypes G1, G2, G3 and G4 when administered as a three-dose series to infants between the ages of 6 to 32 weeks. The first dose should be administered between 6 and 12 weeks of age, with the subsequent doses administered at 4 to 10 week intervals. The third dose should not be given after 32 weeks of age.

ROTAQUE should not be administered to infants with a demonstrated history of hypersensitivity to the vaccine or any component of the vaccine. Infants with Severe Combined Immunodeficiency Disease (SCID) should not receive ROTATEQ. Post-marketing reports of gastroenteritis, including severe diarrhea and prolonged shedding of vaccine virus, have been reported in infants who were administered ROTATEQ and later identified as having SCID.

About Rotavirus

Rotavirus is a leading cause of severe acute gastroenteritis in infants and young children. Rotavirus is highly prevalent and highly contagious, infecting nearly all children by age 5, many more than once, in both developed and developing countries. The virus causes an estimated more than two million hospitalizations among children under age 5 each year. In the U.S., historically rotavirus has been responsible for an estimated 55,000 to 70,000 hospitalizations, more than 200,000 emergency room visits, and approximately 400,000 doctor visits among children under age 5.

Select Safety Information about ROTATEQ

No safety or efficacy data are available from clinical trials regarding the administration of ROTATEQ to infants who are potentially immunocompromised.

No safety or efficacy data are available for administration of ROTATEQ to infants with a history of gastrointestinal disorders.

Vaccine virus transmission from vaccine recipient to non-vaccinated contacts has been reported. Caution is advised when considering whether to administer ROTATEQ to individuals with immunodeficient contacts.

More than 71,000 infants were evaluated in three Phase 3, placebo-controlled clinical trials. Serious adverse events occurred in 2.4 percent of recipients of ROTATEQ when compared to 2.6 percent of placebo recipients within the 42-day period of a dose of ROTATEQ. Hematochezia, reported as a serious adverse event for ROTATEQ compared to placebo, was less than 0.1 percent vs. less than 0.1 percent. The most frequently reported serious adverse events for ROTATEQ, compared to placebo, were bronchiolitis, gastroenteritis, pneumonia, fever, and urinary tract infection.

In a subset of more than 11,000 infants in these trials, the presence of adverse events was reported for 42 days after each dose. Fever was observed at similar rates in vaccine and placebo recipients (42.6 percent vs. 42.8 percent). Adverse events that occurred at a statistically higher incidence within 42 days of any dose among recipients of ROTATEQ, as compared with placebo recipients, were diarrhea (24.1 percent vs. 21.3 percent), vomiting (15.2 percent vs. 13.6 percent), otitis media (14.5 percent vs. 13.0 percent), nasopharyngitis (6.9 percent vs. 5.8 percent), and bronchospasm (1.1 percent vs. 0.7 percent).

In post-marketing experience, intussusception (including death) and Kawasaki disease have been reported in infants who have received ROTATEQ.

ROTATEQ may not protect all vaccine recipients against rotavirus.

About the Advisory Committee on Immunization Practices (ACIP)

The ACIP develops written recommendations for the routine administration of vaccines to children and adults, along with schedules regarding the appropriate dosage and dosing frequency, and contraindications applicable to the vaccines. The goals of the Committee, which consists of 15 experts in immunization and related fields, are to provide advice which will assist the CDC and the nation in reducing the incidence of vaccine-preventable diseases and to increase the safe usage of vaccines and related biological products. The ACIP recommendations do not result in requirements for vaccine administration by individual states or coverage by insurance companies. However, state health authorities and private insurers typically follow the Committee's guidance.

About Merck

Today's Merck is a global healthcare leader working to help the world be well. Merck is known as MSD outside the United States and Canada. Through our prescription medicines, vaccines, biologic therapies, and consumer care and animal health products, we work with customers and operate in more than 140 countries to deliver innovative health solutions. We also demonstrate our commitment to increasing access to healthcare through far-reaching policies, programs and partnerships. For more information, visit www.merck.com.

Forward-Looking Statement

This news release includes "forward-looking statements" within the meaning of the safe harbor provisions of the United States Private Securities Litigation Reform Act of 1995. Such statements may include, but are not limited to, statements about the benefits of the merger between Merck and Schering-Plough, including future financial and operating results, the combined company's plans, objectives, expectations and intentions and other statements that are not historical facts. Such statements are based upon the current beliefs and expectations of Merck's management and are subject to significant risks and uncertainties. Actual results may differ from those set forth in the forward-looking statements.

The following factors, among others, could cause actual results to differ from those set forth in the forward-looking statements: the possibility that the expected synergies from the merger of Merck and Schering-Plough will not be realized, or will not be realized within the expected time period; the impact of pharmaceutical industry regulation and health care legislation; the risk that the businesses will not be integrated successfully; disruption from the merger making it more difficult to maintain business and operational relationships; Merck's ability to accurately predict future market conditions; dependence on the effectiveness of Merck's patents and other protections for innovative products; the risk of new and changing regulation and health policies in the U.S. and internationally and the exposure to litigation and/or regulatory actions.

Merck undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise. Additional factors that could cause results to differ materially from those described in the forward-looking statements can be found in Merck's 2009 Annual Report on Form 10-K and the company's other filings with the Securities and Exchange Commission (SEC) available at the SEC's Internet site (www.sec.gov).

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