FDA Approves ZOSTAVAX®; Merck’s New Vaccine for Prevention of Shingles in Adults Age 60 and Older

**ZOSTAVAX is the first and only medical option for preventing shingles, a painful disease that can occur in anyone who has had chickenpox.**

Whitehouse Station, NJ (PRWEB) May 26, 2006 -- The U.S. Food and Drug Administration (FDA) has approved Merck’s new vaccine ZOSTAVAX®(Zoster Vaccine Live (Oka/Merck)) for prevention of herpes zoster (shingles) in individuals 60 years of age and older. Shingles is a frequently painful disease marked by a blistering rash. Caused by the reactivation of the virus that causes chickenpox, shingles can lead to severe complications including long-term nerve pain (postherpetic neuralgia), which can last for months or even years. ZOSTAVAX is not a treatment for shingles or postherpetic neuralgia. ZOSTAVAX is given as a single dose by injection.

“ZOSTAVAX is the first and only medical option approved for the prevention of shingles,” said William Schaffner, M.D., professor of preventive medicine, Vanderbilt University School of Medicine, Nashville. “Approval of a vaccine against shingles represents a major public health advance for people 60 and older.”

Anyone who has been infected with chickenpox -- that’s more than 90 percent of adults in the United States -- is at risk for developing shingles. The incidence and severity of shingles, as well as the frequency and severity of its complications, increase with age. About 40 to 50 percent of the estimated 1 million cases of shingles that occur in the United States each year occur in people age 60 and older. Shingles can be unpredictable and can occur without warning at any time.

“This vaccine is clinically important because it can prevent a disease that may cause pain in some patients,” said Ann Arvin, M.D., professor of pediatrics, infectious diseases and microbiology and immunology, Stanford University School of Medicine, who studied the vaccine. “ZOSTAVAX is unique because in contrast to other vaccines that help prevent a primary infection, ZOSTAVAX helps prevent reactivation of a virus that’s already inside the body.”

Shingles usually starts as an unusual or painful sensation on one side of the body or face, followed by a blistering rash. Pain from shingles can be mild to severe and may occur just prior to the development of the rash, during the eruption of the rash and as long-term nerve pain (postherpetic neuralgia). Postherpetic neuralgia has been described as tender, burning, throbbing, stabbing, shooting and/or sharp pain. Other complications, such as scarring, allodynia (pain from an innocuous stimulus such as the touch of soft clothing or a light breeze), pneumonia, visual impairment and hearing loss also can occur as the result of shingles. Treating shingles and postherpetic neuralgia can be difficult, often requiring a multifaceted approach.

ZOSTAVAX is contraindicated in persons with a history of anaphylactic/anaphylactoid reaction to gelatin, neomycin, or any other component of the vaccine; with a history of primary or acquired immunodeficiency states including leukemia, lymphomas of any type, or other malignant neoplasms affecting the bone marrow or lymphatic system; with AIDS or other clinical manifestations of infection with human immunodeficiency viruses; and with active untreated tuberculosis. ZOSTAVAX is also contraindicated in persons on immunosuppressive therapy including high-dose corticosteroids and in women who are or may be pregnant. Vaccination with a live, attenuated vaccine, such as ZOSTAVAX, may result in a more extensive vaccine-associated rash or disseminated disease in individuals who are immunosuppressed. Safety and efficacy of

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ZOSTAVAX have not been evaluated in individuals on immunosuppressive therapy, nor in individuals receiving daily topical or inhaled corticosteroids or low-dose oral corticosteroids. The use of ZOSTAVAX in individuals with a previous history of shingles has not been studied.

Studies of ZOSTAVAX

Included More Than 40,000 People

The approval of ZOSTAVAX is based on studies of more than 40,000 people, more than 21,000 of whom received active vaccine. The efficacy and safety of a single dose of ZOSTAVAX was evaluated in the largest of these studies, the landmark Shingles Prevention Study (SPS) of 38,546 men and women age 60 and over who had no previous history of shingles. This randomized, double-blind, placebo-controlled study was a Department of Veterans Affairs study conducted in collaboration with the National Institute of Allergy and Infectious Diseases at the National Institutes of Health and Merck at 22 U.S. research sites.

In the study, participants were randomized to groups given either ZOSTAVAX (N=19,270) or a placebo (N=19,276) and followed for the development of shingles for a median duration of 3.1 years. All subjects with clinically diagnosed shingles were offered antiviral treatment, as well as standard-of-care treatment for pain, as necessary.

ZOSTAVAX significantly reduced the risk of developing shingles compared with placebo by 51 percent (315 cases/5,4 cases per 1,000 person-years) vs. 642 cases (11.1 cases per 1,000 person-years), respectively; p is less than 0.001) in the SPS. Efficacy of ZOSTAVAX for the prevention of shingles was highest for those 60 to 69 years of age and declined with increasing age.

Overall, the benefit of ZOSTAVAX in the prevention of long-term nerve pain from shingles (postherpetic neuralgia) can be primarily attributed to the vaccine’s effect on the prevention of shingles. Vaccination with ZOSTAVAX reduced the incidence of long-term nerve pain from shingles in individuals 70 years of age and older who were vaccinated with ZOSTAVAX but went on to develop shingles. Following completion of the SPS, a separate analysis was conducted to evaluate the reduction in postherpetic neuralgia in the group of individuals who had been vaccinated with ZOSTAVAX but who had developed shingles. In the analysis, ZOSTAVAX reduced the overall incidence of postherpetic neuralgia by a statistically significant 39 percent compared to the placebo group. A statistically significant reduction in postherpetic neuralgia was seen in individuals aged 70 to 79 (55 percent) and a nonstatistically significant reduction in postherpetic neuralgia was seen in those aged 60 to 69 (5 percent) and 80 and older (26 percent) in the analysis.

Safety Profile of ZOSTAVAX

In the Adverse Event Monitoring Study (AEMS), which included a subgroup of individuals from the SPS, vaccine-related injection and systemic adverse events seen in the first 42 days after vaccination in 1 percent or greater of the individuals who received ZOSTAVAX (n=3,345) included headache (1.4 percent) and the following injection-site reactions: erythema (33.7 percent), pain/tenderness (33.4 percent), swelling (24.9 percent), hematoma (1.4 percent), pruritus (6.6 percent), and warmth (1.5 percent). Most of these adverse experiences were reported as mild in intensity.

In the overall study population in the SPS, serious adverse experiences (SAEs) occurred at a similar rate (1.4 percent) in subjects vaccinated with ZOSTAVAX or placebo. In the AEMS, the rate of SAEs was increased in the group who received ZOSTAVAX (1.9 percent) as compared to the placebo group (1.3 percent) in the first 42 days after vaccination. Investigator-determined, vaccine-related serious adverse experiences were reported for two subjects vaccinated with ZOSTAVAX (asthma exacerbation and polymyalgia rheumatica) and three
subjects who received placebo (Goodpasture’s syndrome, anaphylactic reaction, and polymyalgia rheumatica).

In the entire SPS study population, the rates of overall cardiovascular events (0.4 percent) including coronary artery disease related conditions (0.2 percent) were similar in subjects vaccinated with ZOSTAVAXor placebo. In the AEMS of the SPS, in the first 42 days after vaccination, the rate of overall cardiovascular events was higher after ZOSTAVAX(0.6 percent) than after placebo (0.4 percent), including the rate of coronary artery disease-related conditions (ZOSTAVAX,0.3 percent; placebo, 0.2 percent).

Selected Important Information about ZOSTAVAX

ZOSTAVAXis indicated for prevention of herpes zoster (shingles) in individuals 60 years of age and older. ZOSTAVAXis not a treatment for shingles or postherpetic neuralgia. As with any vaccine, vaccination with ZOSTAVAXmay not result in protection of all vaccine recipients.

Patients should be informed of the theoretical risk of transmitting the vaccine virus to close contacts (including household contacts) who may be pregnant and have not had chickenpox or been vaccinated against chickenpox, or contacts who have problems with their immune system. The risk of transmitting the attenuated vaccine virus to a susceptible individual should be weighed against the risk of developing natural shingles that could be transmitted to a susceptible individual.

The duration of protection after vaccination with ZOSTAVAXis unknown. In the SPS, protection with ZOSTAVAXwas demonstrated through four years of follow-up. The need for revaccination has not been defined. ZOSTAVAXis not a substitute for VARIVAX®(Varicella Virus Vaccine Live (Oka/Merck)) and ZOSTAVAXshould not be used in children.

Concurrent administration of ZOSTAVAXand antiviral medications known to be effective against the varicella zoster virus has not been evaluated. Concurrent administration of ZOSTAVAXand other vaccines has not been evaluated.

Merck Commitment to Vaccines

“Merck is pleased to introduce the first and only shingles vaccine – the result of nearly two decades of Merck vaccine research,” said Mark Feinberg, M.D., Ph.D., vice president of policy, public health and medical affairs, Merck Vaccines. “The Company is also very pleased to announce that we will make ZOSTAVAXand all of Merck’s other adult vaccines available free of charge through a new patient assistance program for vaccines for low-income individuals for whom the vaccines are medically appropriate.”

Through this new program, Merck will provide free vaccines to adults who are uninsured and who are unable to afford vaccines. Merck's vaccines will become available through this program in the third quarter of 2006.

Outside the United States, ZOSTAVAXwas approved for licensure in the European Union and in Australia earlier this month, and Merck has filed regulatory applications for ZOSTAVAXin other world markets. Merck will begin to commercialize ZOSTAVAXoutside of the U.S. in 2007. In addition, the FDA and other regulatory agencies around the world are now reviewing applications for GARDASIL® (quadrivalent human papillomavirus types 6, 11, 16, 18, recombinant vaccine), Merck's investigational HPV and cervical cancer vaccine. In February, the FDA approved ROTATEQ®(rotavirus vaccine, live, oral pentavalent), Merck’s rotavirus vaccine.
Pricing and CPT Code for ZOSTAVAX

ZOSTAVAX,a frozen vaccine, is available for ordering by physicians and Merck expects to begin shipping the vaccine soon. The catalog price of ZOSTAVAXis $145.35 purchased as a 10-pack of single-dose vials of lyophilized vaccine with sterile diluent and $152.50 purchased as a single-dose vial of vaccine with sterile diluent.

The American Medical Association has established the Current Procedural Terminology (CPT®) code “CPT 90736 Zoster (shingles) vaccine, live, for subcutaneous use” for ZOSTAVAX. 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 issues.

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 http://www.merck.com.

Merck 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.


Prescribing information and patient product information for ZOSTAVAXis attached. For more information on ZOSTAVAX, visit http://www.ZOSTAVAX.com

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