

## sanofi pasteur Press Release

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### **FDA Advisory Panel Recommends Licensure of sanofi pasteur's ADACEL™ Vaccine for Combined Protection against Tetanus, Diphtheria and Pertussis**

*– Vaccine Leader Looks to Introduce First Pertussis Booster  
for Both Adolescents and Adults in United States –*

**Swiftwater, Pa. – March 15, 2005** – Sanofi pasteur, the vaccines business of the sanofi-aventis Group (NYSE: SNY), announced today that the Vaccines and Related Biological Products Advisory Committee (VRBPAC) of the U.S. Food and Drug Administration (FDA) voted unanimously to recommend licensure of ADACEL™ (Tetanus Toxoid and Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine Adsorbed) Vaccine for protection against tetanus, diphtheria and pertussis in adolescents and adults aged 11-64 years.

ADACEL vaccine is the first booster to address pertussis protection across a wide range of ages including adolescents and adults. These age groups are at a growing risk of contracting and transmitting the disease.

The number of reported cases of pertussis – commonly known as whooping cough – continues to rise at a rate of great concern to the public health and medical communities. The U.S. Centers for Disease Control and Prevention (CDC) has received 19,000 case reports for 2004, a nearly 40 percent increase over 2003, and the highest number in four decades. Various studies indicate that the actual number of pertussis cases is many times greater than what is reported.

Approximately two-thirds of all cases occur in adolescents and adults. Although pertussis in adolescents and adults is often thought of as relatively mild, many in these age groups who contract the disease experience prolonged coughing, vomiting, missed school or work, and various complications. Due to similarities of symptoms, pertussis may initially be mistaken for other viral illnesses such as bronchitis, influenza, or even the common cold. In fact, it is within the first two weeks, often before a noticeable cough develops, when pertussis is most contagious.

Additionally, pertussis is easily transmitted to unimmunized or partially immunized infants and young children who are more vulnerable to serious pertussis-related complications or death. In effect, preventing pertussis in adolescents and adults could provide another means of preventing the spread of the disease, particularly to infants and young children.

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“The dramatic increase in pertussis and the growing number of outbreaks are a critical reminder that we need to bring this serious disease under control,” said David R. Johnson, MD, MPH, director, scientific and medical affairs, sanofi pasteur. “We are very pleased that the Advisory Committee has recognized the need for ADACEL vaccine for adolescents and adults because it will be an expansion of sanofi pasteur’s pertussis portfolio that will represent a new approach to disease prevention in the U.S.”

Although the FDA is not bound by the Advisory Committee’s recommendation, the agency considers it carefully when deciding whether to license a vaccine for marketing.

In making its recommendation, the FDA Advisory Committee reviewed the results of four principle clinical studies that included more than 7200 individuals who were evaluated for safety. The immunogenicity profile of ADACEL vaccine was documented in a randomized subset of participants enrolled in the studies. Across the four trials, a total of 4,342 ADACEL and Td vaccine recipients were evaluated for their immune responses to vaccination.

ADACEL vaccine is currently licensed and marketed in Canada and Germany.

### **Risk of Pertussis**

Pertussis is a highly contagious respiratory disease marked by severe coughing. Its common name, whooping cough, comes from the “whoop” sound patients make when they try to inhale during or after a severe coughing spell.

There are both severe and milder forms of pertussis. Although pertussis can occur at any age, severe pertussis disease usually occurs in infants and young children who have not been fully vaccinated and who are at higher risk for serious complications – such as pneumonia and seizures – and death. The pertussis immunity induced by early childhood vaccinations or by natural disease wears off, leaving adolescents and adults once again susceptible to pertussis. While they may not always experience the debilitating effects of the disease that infants do, infected adolescents and adults often have prolonged illness and can easily transmit the illness to unimmunized and partially immunized infants and young children. Additionally, adults older than 55 years of age may be at considerable risk for certain complications associated with pertussis.

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Mild pertussis disease is difficult to diagnose because its symptoms are not distinctive; usually a prolonged cough is present, but without the “whoop.” Although infants and young children may experience mild pertussis disease, it is more often associated with adolescents and adults.

“While adolescent and adult patients may be spared the debilitating effects of pertussis, the fact that their disease is often not readily diagnosed means that they may unwittingly spread it to others,” said Dr. Johnson.

### **About Tetanus, Diphtheria, Pertussis**

Tetanus is a severe, frequently fatal disease caused by an exotoxin produced by bacteria (*Clostridium tetani*). The disease, characterized by generalized rigidity and convulsive spasms of skeletal muscles, causes paralysis, and usually starts at the top of the body and works its way down. “Lockjaw,” as the disease is sometimes called, is often the first symptom, followed by stiffness in the neck and difficulty swallowing. Muscle spasms may occur frequently, lasting for several minutes and persisting for up to a month. Symptoms of tetanus can appear anywhere from three days to three weeks after exposure to the bacteria and may be accompanied by fever, sweating, elevated blood pressure and rapid heartbeat. The bacteria that cause tetanus are widespread and are found in soil and in the intestinal tracts of animals and humans. It usually enters the body through a wound or opening in the skin. Virtually all of the cases of tetanus disease occurring in the U.S. are in adults not up-to-date with booster vaccinations.

Diphtheria is caused by exposure to bacteria (*Corynebacterium diphtheriae*) from an infected person and usually affects the tonsils, throat, nose and/or skin. It is passed from person to person by droplet transmission, usually by breathing in diphtheria bacteria after an infected person has coughed, sneezed, or even laughed. It can also be spread by handling used tissues or by drinking from a glass used by an infected person. Symptoms usually appear two to five days after infection and begin very much like a common cold. However, symptoms can progress as a membrane grows and covers anywhere from a small patch to most of the throat, potentially blocking the airway. The infection releases a toxin that can lead to heart failure and paralysis. If enough toxin is absorbed into the bloodstream, coma or even death can occur in as little as a week. Diphtheria occurs rarely in this country, but is occasionally imported from countries where it is endemic. Ongoing vaccination to protect against diphtheria continues to be recommended.

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Pertussis, a highly contagious disease of the respiratory tract, is caused by bacteria (*Bordetella pertussis*) found in the mouth, nose and throat of an infected person. Pertussis is primarily spread when someone with the disease coughs in close proximity to a person who is susceptible. Classic, or severe, pertussis, as defined by the World Health Organization, consists of at least 21 days of cough illness (with the cough coming in spasms or paroxysms), associated whoops or post-cough vomiting, and laboratory confirmation. Mild pertussis is any laboratory-confirmed pertussis disease that is less than classic disease. Pertussis can occur at any age. Approximately two thirds of the cases reported in the US occur in adolescents and adults, while the majority of the remaining reported cases affect children under 6 months of age. Pertussis is less common among children aged 6 months through 10 years, who are protected by existing vaccination programs. For young children, pertussis disease can result in significant morbidity, hospitalization, serious long-term complications, and death. Pertussis immunity, whether from childhood vaccination or natural disease, is not lifelong; it must be boosted for adolescents and adults to be protected.

### **About sanofi-aventis**

The sanofi-aventis Group is the world's third-largest pharmaceutical company, ranking number one in Europe. Backed by a world-class R&D organization, sanofi-aventis is developing leading positions in seven major therapeutic areas: cardiovascular disease, thrombosis, oncology, metabolic diseases, central nervous system, internal medicine, and vaccines. The sanofi-aventis Group is listed in Paris (EURONEXT: SAN) and in New York (NYSE: SNY).

Sanofi pasteur, the vaccines business of the sanofi-aventis Group, sold 950 million doses of vaccine in 2004, making it possible to protect more than 500 million people across the globe, which is about 1.4 million per day. The company offers the broadest range of vaccines, providing protection against 20 bacterial and viral diseases. For more information, please visit: [www.sanofipasteur.com](http://www.sanofipasteur.com)

### **Forward Looking Statement**

*This press release contains forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995. Forward-looking statements are statements that are not historical facts. These statements include financial projections and estimates and their underlying assumptions, statements regarding plans, objectives and expectations with respect to future operations, products and services, and statements regarding future performance. Forward-looking statements are generally identified by the words "expect," "anticipates,"*

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*“believes,” “intends,” “estimates” and similar expressions. Although sanofi-aventis’ management believes that the expectations reflected in such forward-looking statements are reasonable, investors are cautioned that forward-looking information and statements are subject to various risks and uncertainties, many of which are difficult to predict and generally beyond the control of sanofi-aventis, that could cause actual results and developments to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements. These risks and uncertainties include those discussed or identified in the public filings with the SEC and the AMF made by sanofi-aventis and Aventis, including those listed under “Forward-Looking Statements” and “Risk Factors” in sanofi-aventis’s annual report on Form 20-F for the year ended December 31, 2003 and those listed under “Cautionary Statement Regarding Forward-Looking Statements” and “Risk Factors” in Aventis’s annual report on Form 20-F for the year ended December 31, 2003. Other than as required by applicable law, sanofi-aventis does not undertake any obligation to update or revise any forward-looking information or statements.*

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