

U.S. FDA Licenses Sanofi Pasteur's New Pediatric Combination Vaccine, Pentacel[®]

- Pentacel[®] vaccine is the first 5-in-1 pediatric combination for immunization against diphtheria, tetanus, pertussis, polio and *Haemophilus influenzae* type b (Hib) -


Swiftwater, PA - Lyon, France - June 23, 2008 - Sanofi Pasteur, the vaccines division of the sanofi-aventis Group, announced today that the U.S. Food and Drug Administration (FDA) has licensed Pentacel[®], Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed, Inactivated Poliovirus and *Haemophilus b* Conjugate (Tetanus Toxoid Conjugate) Vaccine. Pentacel[®] vaccine is indicated for active immunization against diphtheria, tetanus, pertussis, poliomyelitis, and invasive disease due to *Haemophilus influenzae* type b (Hib). Pentacel[®] vaccine is approved for use in infants and children 6 weeks through 4 years of age (prior to fifth birthday).

Pentacel[®] vaccine is the first and only four-dose diphtheria, tetanus, and acellular pertussis (DTaP)-based combination vaccine for use in infants and young children in the U.S. that includes both poliovirus and Hib antigens.

Pentacel[®] vaccine is approved for administration as a four-dose series at 2, 4, 6 and 15-18 months of age. The first dose may be given as early as 6 weeks of age. According to the current Recommended Childhood Immunization Schedule of the U.S. Centers for Disease Control and Prevention (CDC), up to 23 injections are needed by the time a child reaches 18 months of age with single-entity vaccines. The use of Pentacel[®] vaccine could reduce that number of shots by seven.

"Pentacel[®] vaccine will help simplify the immunization schedule by reducing the number of injections infants and young children will receive in their first two years of life," said Wayne Pisano, President and Chief Executive Officer, sanofi pasteur. Pentacel[®] vaccine has been used in Canada for a decade and is licensed in seven other countries. *"We are pleased that the U.S. FDA has now taken this important step, to make the convenience of Pentacel[®] vaccine available to health-care providers and parents in the U.S.,"* Pisano added.

"The FDA approval of Pentacel[®] vaccine is great news for parents and pediatricians who want to reduce the stress of well-baby visits," said Tina Q. Tan, M.D., infectious disease specialist, Children's Memorial Hospital, Chicago. *"Pertussis disease continues to remain a threat to young infants, who are at the highest risk for severe complications and death. With a four-dose primary series of Pentacel[®] vaccine, pediatricians can reduce the number of vaccination shots while providing protection against five diseases, including pertussis."*



Pentacel[®] vaccine is also the first five-component (pentavalent) pediatric combination vaccine in the U.S. to contain sanofi pasteur's five acellular pertussis antigens, which are also used in its DTaP vaccine for children (DAPTACEL^{®a} vaccine, licensed in 2002) and its tetanus, diphtheria, and acellular pertussis (Tdap) vaccine for adults and adolescents (Adacel^{®b} vaccine, licensed in 2005). Pertussis is commonly known as whooping cough because of the sound some patients—especially children—make while gasping for air during coughing spells.

The FDA licensure of Pentacel[®] vaccine is based on the results of multi-center clinical studies conducted in the U.S. and Canada involving more than 5,000 children who received at least one dose of Pentacel[®] vaccine. The immunogenicity of Pentacel[®] vaccine was compared to separately administered DAPTACEL, IPOL^{®c} and ActHIB^{®d} vaccines (studies P3T06 and M5A10), as well as to other single-entity vaccine formulations (study 494-01). The safety of Pentacel[®] vaccine was compared both to separately administered DAPTACEL, IPOL and ActHIB vaccines (study P3T06) and to other single-entity vaccine formulations (study 494-01).

In clinical studies, local and systemic reactions following administration of Pentacel[®] vaccine were reported at rates consistent with those of the separately administered vaccines used in each trial. The most common local and systemic adverse reactions to Pentacel[®] vaccine include injection site redness, swelling and tenderness; fever, fussiness and crying. Other adverse reactions may occur. Known systemic hypersensitivity reaction to any component of Pentacel[®] vaccine or a life-threatening reaction after previous administration of the vaccine or a vaccine containing the same substances are contraindications to vaccination.

The decision to give Pentacel[®] vaccine should be based on the potential benefits and risks; if Guillain-Barré syndrome has occurred within 6 weeks of receipt of a prior vaccine containing tetanus toxoid; or if adverse events have occurred in temporal relation to receipt of pertussis-containing vaccine. Encephalopathy within 7 days of administration of a previous dose of a pertussis-containing vaccine or a progressive neurologic disorder is a contraindication. Vaccination with Pentacel[®] vaccine may not protect all individuals.

Before administering Pentacel[®] vaccine, please see accompanying full Prescribing Information.

The full Prescribing Information for Pentacel[®] vaccine is available on www.pentacel.com and www.vaccineshoppe.com. More than 14 million doses of Pentacel[®] vaccine have been distributed in Canada since 1997. Pentacel[®] vaccine is expected to be available for distribution in the U.S. this summer.

Sanofi Pasteur's U.S. operations in Swiftwater, PA have long been committed to providing vaccines to prevent childhood diseases. In 1987, it licensed the first Hib conjugate vaccine. And in 1996, it was the first company to license a DTaP vaccine for use in infants (Tripedia^{®e} vaccine). In 2005, sanofi pasteur continued its tradition of innovation by introducing Menactra^{®f} vaccine to protect against meningococcal disease, and Adacel vaccine as a booster dose for protection against tetanus, diphtheria and pertussis in both adults and adolescents 11-64 years of age.

About sanofi-aventis

Sanofi-aventis, a leading global pharmaceutical company, discovers, develops and distributes therapeutic solutions to improve the lives of everyone. Sanofi-aventis is listed in Paris (EURONEXT PARIS: SAN) and in New York (NYSE: SNY).

Sanofi Pasteur, the vaccines division of sanofi-aventis Group, provided more than 1.6 billion doses of vaccine in 2007, making it possible to immunize more than 500 million people across the globe. A world leader in the vaccine industry, sanofi pasteur offers the broadest range of vaccines protecting against 20 infectious diseases. The company's heritage, to create vaccines that protect life, dates back more than a century. Sanofi Pasteur is the largest company entirely dedicated to vaccines. Every day, the company invests more than EUR1 million in research and development. For more information, please visit: www.sanofipasteur.com or www.sanofipasteur.us.



Forward Looking Statements

This press release contains forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995, as amended. 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, intentions and expectations with respect to future events, operations, products and services, and statements regarding future performance. Forward-looking statements are generally identified by the words “expects,” “anticipates,” “believes,” “intends,” “estimates,” “plans” 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, including those listed under “Risk Factors” and “Cautionary Statement Regarding Forward-Looking Statements” in sanofi-aventis’ annual report on Form 20-F for the year ended December 31, 2007. 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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^a The true name for DAPTACEL vaccine is: Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed.

^b The true name for Adacel vaccine is: Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine Adsorbed.

^c The true name for IPOL vaccine is: Poliovirus Vaccine Inactivated.

^d The true name for ActHIB vaccine is: Haemophilus b Conjugate Vaccine (Tetanus Toxoid Conjugate).

^e The true name for Tripedia vaccine is: Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed.

^f The true name for Menactra vaccine is: Meningococcal (Groups A, C, Y and W-135) Polysaccharide Diphtheria Toxoid Conjugate Vaccine.