

SANOFI-AVENTIS  
Form 6-K  
October 22, 2007

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

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**FORM 6-K**

**REPORT OF FOREIGN PRIVATE ISSUER**

**PURSUANT TO RULE 13a-16 OR 15d-16**

**UNDER THE SECURITIES EXCHANGE ACT OF 1934**

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For the month of October 2007

Commission File Number: 001-31368

**SANOFI-AVENTIS**

(Translation of registrant's name into English)

174, avenue de France, 75013 Paris, FRANCE

(Address of principal executive offices)

Indicate by check mark whether the registrant files or will file annual reports under cover Form 20-F or Form 40-F.

Form 20-F

Form 40-F

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

Indicate by check mark whether the registrant by furnishing the information contained in this Form is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.

Yes

No

If  Yes marked, indicate below the file number assigned to the registrant in connection with Rule 12g3-2(b): 82-\_\_\_\_\_

In October 2007, sanofi-aventis issued the press releases attached hereto as Exhibit 99.1, 99.2 and 99.3 which are incorporated herein by reference.

**Exhibit List**

<u>Exhibit No.</u>	<u>Description</u>
Exhibit 99.1	Press release dated October 18, 2007: Sanofi Pasteur receives FDA approval of meningococcal vaccine for children.
Exhibit 99.2	Press release dated October 22, 2007: Taxotere <sup>®</sup> receives positive opinion from the Committee for medicinal Products for Human use (CHMP) recommending approval in the European Union for induction treatment for locally advanced Head and Neck cancer.
Exhibit 99.3	Press release dated October 22, 2007: Plavix <sup>®</sup> indications expanded in Japan to include patients with Acute Coronary Syndrome for whom percutaneous coronary intervention is being planned.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Dated: October 22, 2007

SANOFI-AVENTIS

By           /S/ Patricia Kodyra          

Name: Patricia Kodyra

Title: Associate Vice President

Financial and Securities Law

**Exhibit Index**

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Sanofi Pasteur: [www.sanofipasteur.com](http://www.sanofipasteur.com)  
Media Relations: Tel.: + 33 4 37 37 50 38  
Media Relations US: Tel.: + 1 570 839 44 46

Swiftwater, PA, October 18, 2007

## Sanofi Pasteur receives FDA approval of meningococcal vaccine for children

### Menactra<sup>®</sup> meningococcal conjugate vaccine approved for use in children 2 years through 10 years of age

Sanofi Pasteur, the vaccines division of sanofi-aventis Group, announced today that the U.S. Food and Drug Administration (FDA) has granted licensure to expand the indication for its meningococcal conjugate vaccine, Menactra<sup>®</sup> (Meningococcal [Groups A, C, Y and W-135] Polysaccharide Diphtheria Toxoid Conjugate Vaccine), to include children 2 years through 10 years of age.

Menactra<sup>®</sup> vaccine is the first and only quadrivalent conjugate vaccine licensed in the U.S. for the prevention of meningococcal disease. The vaccine first received FDA licensure in 2005 for immunization of adolescents and adults 11 years through 55 years of age. Menactra vaccine offers protection against four of the five most common serogroups of the bacterium that cause meningococcal infection, *Neisseria meningitidis* serogroups A, C, Y and W-135. No vaccine is available in the United States for protection against infection from serogroup B.

*We have been waiting for this expansion of use of Menactra<sup>®</sup> to younger children, since they too are at risk and may benefit from the vaccine. Meningococcal disease is serious and no healthy child should have to risk permanent disability, or even death, from this vaccine-preventable disease. About half of the cases in children 2 years through 5 years, and two-thirds in those 6 years through 11 years can potentially be prevented through vaccination in the United States* said Michael Pichichero, MD, professor of microbiology/immunology, pediatrics and medicine, University of Rochester Medical Center.

#### Clinical Studies

The FDA's decision to license Menactra<sup>®</sup> vaccine for children 2 years through 10 years of age was based on safety and immunogenicity data from two large clinical studies. Both studies were randomized, multi-center, active-controlled, modified double-blind clinical studies of children 2 years through 10 years of age comparing the safety and immunogenicity of Menactra<sup>®</sup> vaccine to Menomune<sup>®</sup>-A/C/Y/W-135, Meningococcal Polysaccharide Vaccine, Groups A, C, Y and W-135 Combined. A third multi-center, open-label study of children 4 years through 6 years of age evaluated the antibody memory response to the vaccine in children who had been vaccinated previously with Menactra<sup>®</sup> vaccine approximately two years earlier.

Data from the studies indicated that the vaccine was safe and immunogenic for children 2 years through 10 years of age. Immune responses were significantly greater for all four serogroups in those who received Menactra<sup>®</sup> vaccine than those who received Menomune-A/C/Y/W-135 vaccine. In addition, compared to Menomune-A/C/Y/W-135 vaccine, Menactra<sup>®</sup> vaccine resulted in longer-term persistence of bactericidal antibody, production of high avidity antibody, and the establishment of immune memory. No clinically significant adverse events were identified after a six-month controlled follow-up. In the studies, immediate reactions were uncommon and consisted primarily of local redness at or near the injection site. Reactions were reported for the most part as mild and of short duration. Solicited systemic reactions were similar among the study groups and were described for the most part as mild, reversible and of short duration. The most common solicited complaints among children 2 years through 10 years of age were injection site pain and irritability.



### **Immunization Recommendations**

Since its introduction in 2005 there has been strong acceptance by health-care providers and consumers for Menactra<sup>®</sup> vaccine. This was evident by the increased uptake following new vaccination recommendations issued by the Centers for Disease Control and Prevention (CDC) in June 2007 calling for meningococcal immunization for all adolescents 11 years through 18 years of age.

Sanofi Pasteur will continue to work closely with the CDC's Advisory Committee on Immunization Practices regarding recommendations for children younger than 11 years of age, now that FDA has licensed Menactra<sup>®</sup> vaccine for use in children 2 years through 10 years of age.

For more information about Menactra<sup>®</sup> vaccine, please visit [www.sanofipasteur.us](http://www.sanofipasteur.us). Immunization providers can order Menactra vaccine by visiting [www.vaccineshoppe.com](http://www.vaccineshoppe.com) or calling 1-800-VACCINE (1-800-822-2463).

### **About Meningococcal Disease**

Meningococcal disease is a rare but serious bacterial infection that strikes between 1,400 and 2,800 Americans every year, causing meningitis or sepsis in the majority of cases. Approximately 10 percent of individuals who contract meningococcal disease will die. Of those who survive, up to one in five suffer permanent disabilities such as hearing loss, neurological damage and limb amputations. Meningococcal disease often begins with symptoms that can be mistaken for common viral illnesses, such as the flu. But unlike more common infections, meningococcal disease can progress very rapidly and kill an otherwise healthy young person in 48 hours or less.

### **Indication**

Menactra<sup>®</sup> vaccine is indicated for active immunization against invasive meningococcal disease caused by *N. meningitidis* serogroups A, C, Y, and W-135 in people 2 years through 55 years of age. Menactra vaccine will not stimulate protection against infection, caused by *N. meningitidis* other than serogroups A, C, Y, and W-135.

### **Safety Information**

There are risks associated with all vaccines. The most common local and systemic adverse reactions to Menactra vaccine include injection site pain, redness, and induration; headache, fatigue, and malaise. Other adverse reactions may occur. Menactra vaccine is contraindicated in persons with known hypersensitivity to any component of the vaccine or to latex, which is used in the vial stopper. Guillain-Barré syndrome (GBS) has been reported in temporal relationship following administration of Menactra vaccine. Persons previously diagnosed with GBS should not receive Menactra<sup>®</sup> vaccine. As with any vaccine, vaccination with Menactra<sup>®</sup> vaccine may not protect 100 percent of individuals.

### **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: SAN) and in New York (NYSE: SNY).

Sanofi Pasteur, the vaccines division of sanofi-aventis Group, provided more than a billion doses of vaccine in 2006, 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](http://www.sanofipasteur.com) or [www.sanofipasteur.us](http://www.sanofipasteur.us)

**Forward Looking Statements**

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**Sanofi Pasteur**

Pascal Barollier

Media Relations

Tel : + 33-(0)4-37-37-51-41

pascal.barollier@sanofipasteur.com

**Sanofi Pasteur**

Len Lavenda

Media Relations US

Tel: + 1-570-839-4446

len.lavenda@sanofipasteur.com



Paris, October 22, 2007

**Taxotere<sup>®</sup> receives positive opinion  
from the Committee for Medicinal Products  
for Human Use (CHMP) recommending approval  
in the European Union for induction treatment  
for locally advanced Head and Neck cancer**

Sanofi-aventis announced today that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has granted a positive opinion for the use of Taxotere<sup>®</sup> (docetaxel) in combination with cisplatin and 5-fluorouracil for the induction treatment of patients with locally advanced squamous cell carcinoma of the head and neck (SCCHN). The CHMP based its decision on the significant improvement of survival demonstrated by the results of the phase III trial, TAX 324, (71 months with the Taxotere<sup>®</sup>-based regimen versus 30 months with the control regimen).

The US Food and Drug Administration (FDA) approved Taxotere<sup>®</sup> for this additional indication on September 28, 2007.

*For many years, we have waited for a new therapeutic option for this very difficult pathology,* said Marshall Posner, MD, Medical Director of the Head and Neck Oncology Program at Dana-Farber Cancer Institute in Boston. *The survival improvement seen with this Taxotere<sup>®</sup>-based regimen is extraordinary for locally advanced squamous cell carcinoma, and will provide a new, multidisciplinary approach to the management of our patients.*

Taxotere<sup>®</sup> is currently approved in 5 different cancer types in Europe and the US and this new indication for Taxotere<sup>®</sup> is the 11<sup>th</sup> in Europe (the 8<sup>th</sup> in the US).

**Approval Based on Clinical Trial Tax 324**

Patients were treated with for three cycles of chemotherapy every three weeks with either TPF (Taxotere 75 mg/m<sup>2</sup> plus cisplatin 100 mg/m<sup>2</sup> and 5-fluorouracil 1000 mg/m<sup>2</sup> a day for four days) or PF (intravenous cisplatin 100 mg/m<sup>2</sup> followed by 5-fluorouracil 1000 mg/m<sup>2</sup> a day for five days), the standard therapy. Both groups of patients were then given weekly chemotherapy (carboplatin) together with radiation therapy for seven weeks, followed by surgery for those patients identified as candidates. The study was designed primarily to evaluate overall survival. Secondary endpoint included progression-free survival, response rates, toxicity, quality of life and clinical benefits.

Patients entering TAX 324 had tumors of the oropharynx, larynx, hypopharynx or oral cavity that either could not be removed, were considered potentially operable but unlikely to be cured with surgery, or could not be removed in order to preserve larynx function. Participants in the trial had either stage III or IV SCCHN with no distant metastases.

Among patients treated with Taxotere<sup>®</sup>-based therapy (TPF, n=255) overall survival was significantly improved compared to patients receiving just cisplatin and 5-fluorouracil (PF, n=246); the relative risk of death was 30% lower (HR 0.70; p=0.0058). Patients treated with TPF had a longer median overall survival of 71 months vs. 30 months for patients receiving PF, representing a more than three year improvement in median OS for patients treated with TPF. Survival at three years was 62% in the TPF arm compared to 48% in the PF arm.

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**Media Relations:** Tel. : (+) 33 1 53 77 44 50

E-mail : [media-relations@sanofi-aventis.com](mailto:media-relations@sanofi-aventis.com)

**Investor Relations :** Tel. : (+) 33 1 53 77 45 45

E-mail : [IR@sanofi-aventis.com](mailto:IR@sanofi-aventis.com)

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Overall, the incidence of grade 3/4 toxicity was 65% in the Taxotere<sup>®</sup> arm (TPF) compared to 62% in the group receiving cisplatin and fluorouracil (PF). Patients treated with TPF had more febrile neutropenia (12% vs 7%), neutropenic infection (12% vs 8%), and grade 3/4 neutropenia (84% vs. 56%), alopecia (4% vs 1%) and diarrhea (7% vs. 3%) than those in the PF group. Patients in the PF group had more grade 3/4 thrombocytopenia (11% vs. 4%), stomatitis (27% vs. 21%), lethargy (10% vs. 5%) and vomiting (10% vs. 8%). The incidence of other grade 3/4 events was similar between the two groups, such as nausea, anorexia and constipation. The incidence of treatment delays was significantly lower in the TPF group indicating a diminution of the toxicity in this treatment arm. Patients treated in the TPF arm received a prophylactic antibiotherapy in order to better control the hematological toxicity, mainly febrile neutropenia.

### **Head and Neck Cancer, a Deadly Disease**

More than 640,000 people worldwide are diagnosed with head and neck cancer each year, and more than 350,000 die from the disease annually. Head and neck cancer is a group of many related diseases that mostly begin in the cells that line the mucosal surfaces in the head and neck area such as the mouth, tongue, tonsils, throat and voicebox. The term encompasses cancers of the oral cavity, salivary glands, paranasal sinuses and nasal cavity, pharynx, larynx, and lymph nodes in the upper part of the neck.

### **About Taxotere<sup>®</sup>**

Taxotere<sup>®</sup> is currently approved in 5 different cancer types in Europe and the US:

#### **In Breast Cancer**

In the United States and in Europe Taxotere<sup>®</sup> is approved to treat patients with locally advanced or metastatic breast cancer after failure of prior chemotherapy. It is also approved in Europe in combination with doxorubicin for patients who have received prior cytotoxic therapy for this condition and in combination with capecitabine after failure of cytotoxic therapy which would have included anthracycline. In the adjuvant setting (post surgery) it is approved in the U.S. and in Europe in combination with doxorubicin and cyclophosphamide (TAC regimen) for the treatment of patients with operable, node-positive breast cancer. Finally, in Europe, Taxotere<sup>®</sup> is approved in combination with trastuzumab for the treatment of patients with metastatic breast cancer- overexpressing HER2 receptor.

#### **In Lung Cancer**

In the U.S. and in Europe, Taxotere<sup>®</sup>, in combination with cisplatin, is approved for the treatment of patients with unresectable locally advanced or metastatic non-small cell lung cancer (NSCLC) who have not received prior chemotherapy, and it also is approved, as a single agent, for patients with unresectable locally advanced or metastatic NSCLC after failure of prior platinum-based chemotherapy.

#### **In Prostate Cancer**

Taxotere<sup>®</sup> is approved for use in combination with prednisone as a treatment for androgen independent (hormone-refractory) metastatic prostate cancer in the U.S. and in Europe.

#### **In Gastric (Stomach) Cancer**

The FDA and the Committee for Medicinal Products for Human Use (CHMP) of the European Agency for the Evaluation of Medicinal Products (EMA) approved in March 2006, the use of Taxotere<sup>®</sup> Injection Concentrate in combination with cisplatin and 5-fluorouracil for the treatment of patients with advanced stomach (gastric) cancer, including cancer of the gastro oesophageal (GE) junction, who have not received prior chemotherapy for advanced disease.

#### **In Head and Neck Cancer**

In October 2006, the European Medicines Agency (EMA) and the FDA approved Taxotere<sup>®</sup> (docetaxel) Injection Concentrate in combination with cisplatin and fluorouracil for the induction treatment of patients with inoperable locally advanced squamous cell carcinoma of the head and neck (SCCHN). In September 2007, the FDA approved Taxotere<sup>®</sup> in combination with cisplatin and 5-fluorouracil for the induction therapy of patients with locally advanced squamous cell carcinoma of the head and neck (SCCHN) prior to chemoradiotherapy and surgery.



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Paris, October 22, 2007

Contact: Philippe Barquet +33 6 70 48 61 28

Plavix<sup>®</sup> indications expanded in Japan  
to include patients with Acute Coronary  
Syndrome for whom percutaneous  
coronary intervention is being planned

Sanofi-aventis announced today that the Japanese Ministry of Health, Labor and Welfare (MHLW) has granted approval for a Supplemental New Drug Application (sNDA) for the indication of Acute coronary syndrome (unstable angina pectoris, non-ST elevation myocardial infarction) for which percutaneous coronary intervention (PCI) is being planned for Plavix<sup>®</sup> (clopidogrel).

Approximately 100,000 patients develop an acute coronary syndrome (ACS) and elect to undergo PCI every year in Japan - where Plavix<sup>®</sup> is now the first drug approved in this indication - , the largest number of patients in the world outside of the United States.

*We are pleased that the innovative therapy, Plavix<sup>®</sup> is now available to physicians in Japan, offering them a new treatment option with proven outcomes and safety across ACS patients with planned PCI,* said Hanspeter Spek, Executive Vice-President Pharmaceutical Operation of sanofi-aventis.

In Japan, this new cardiology (ASC) extension completes the recent approval (May 2006) in the reduction of recurrence of stroke for which the 2 weeks-prescription-only-limitation has been lifted in May 2007, as result of the favorable one year safety assessment.

The efficacy and safety profile of Plavix<sup>®</sup> is well established in multiple large-scale Japanese and international landmark clinical trials involving more than 100,000 patients as well as from real-life clinical experience in more than 70 millions patients worldwide including Japan.

Japanese guidelines<sup>1, 2</sup> suggest that Plavix<sup>®</sup> can fill an important medical need for patients with UA-NSTEMI. Outside Japan, Plavix<sup>®</sup> is also recommended in multiple national and international guidelines (US [ACC/AHA] and European [ESC])<sup>3,4,5,6,7,8</sup> for ACS, heart attack, recent MI, stroke and / or P.A.D patients at risk for future atherothrombotic events as a standard treatment for millions of patients at cardiovascular risk.

Outside Japan, Plavix<sup>®</sup> is the only widely approved antiplatelet agent used in monotherapy for prevention of atherothrombotic events in patients with recent myocardial infarction (hear attack), recent ischaemic stroke or established peripheral arterial disease, and in combination with acetylsalicylic acid for the treatment of patients with acute coronary syndrome (unstable angina or NSTEMI) including those who are to be managed medically and those managed with PCI (with or without stent) and for STEMI patients.

Plavix<sup>®</sup> is one of the most studied cardiovascular medications available to patients with short and long term clinical benefit, and after a decade of prescriptions, It remains the oral antiplatelet therapy with the broadest range of indications worldwide.

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**Media Relations:** Tel. : (+) 33 1 53 77 44 50

E-mail : [media-relations@sanofi-aventis.com](mailto:media-relations@sanofi-aventis.com)

**Investor Relations :** Tel. : (+) 33 1 53 77 45 45

E-mail : [IR@sanofi-aventis.com](mailto:IR@sanofi-aventis.com)

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### About Plavix®

Plavix® also marketed as Iscover® is an antiplatelet agent which prevents platelets from sticking together and forming clots in the arteries. Plavix® was first authorized in the United States in 1997 and the European Union in 1998 and has been prescribed to more than 70 millions patients worldwide.

In Japan, in addition to the new approval for acute coronary syndrome (unstable angina pectoris, non-ST elevation myocardial infarction) for which percutaneous coronary intervention (PCI) is planned, Plavix® is also approved for reduction of recurrence after ischemic cerebrovascular disorder (excluding cardiogenic cerebral embolism) one of the 3 major causes of death in Japan.

The efficacy and safety profile of Plavix® have been established through landmark clinical trials including more than 100 000 patients worldwide. Outside Japan, Plavix® has shown favourable tolerability profile as compared to ASA and an acceptable increase in major bleedings when used in combination with ASA (no statistical difference when only PCIs are considered).

In Japan Plavix® is marketed by sanofi-aventis K.K. Plavix® is marketed in more than 100 countries by sanofi-aventis (Paris Bourse:EURONEXT:SAN; New York:NYSE:SNY) and BMS (NYSE:BMJ).

### About Acute Coronary Syndrome

Acute coronary syndrome (ACS) is an umbrella term used to describe a group of clinical diagnoses caused by narrowing of the coronary arteries and covers any group of clinical symptoms compatible with acute myocardial ischemia, caused by an imbalance between myocardial oxygen supply and demand from coronary artery disease.

Unstable angina, non-ST segment elevation myocardial infarction (myocardial infarction which does not show ST elevation in ECG), and acute myocardial infarction are considered to be the series of the pathological condition referred to as acute myocardial ischemia as the clinical syndrome. These three symptoms and sudden cardiac death are collectively referred to as acute coronary syndrome.

Immediate treatment is required for all ACS. The treatment approach is multifaceted and aims to try and protect the affected heart muscle from further damage, reinstate blood flow through the artery and reduce the heart's demand for oxygen. Restoration of blood to the heart (reperfusion) can be achieved either via the use of certain drugs (fibrinolytics), used to break down blood clots, or mechanically by surgery (i.e. Percutaneous Coronary Intervention (PCI)). Pharmacological options for the treatment ACS include the use of antiplatelet agents to help prevent platelets from sticking together and forming clots, and anticoagulants to prevent blood clotting. Anticoagulants prevent clots from growing and new ones from forming, but they do not dissolve clots.

### About Atherothrombosis

Atherothrombosis is the underlying cause of life-threatening events such as heart attacks and ischemic stroke. It is a progressive disease process in which there is an unpredictable and sudden rupture of an atherosclerotic plaque. The rupture, fissure or erosion of these plaques activates platelets in the blood to form a clot (thrombus) and which can partially or completely block arteries, resulting in atherothrombotic events.

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**References:**

1 Guidelines for Management of Acute Coronary Syndrome without Persistent ST segment Elevation (JCS 2002, Circulation Journal Vol.66, Suppl. IV, 2002, pp.1123-1163)

2 Guidelines for management of anticoagulant and antiplatelet therapy in cardiovascular disease (JCS 2004, Circulation Journal Vol.68, Suppl. IV, 2004, pp.1153-1219)

3 The American College of Cardiology/The American Heart Association

4 ACC/AHA 2007 Guidelines for the Management of Patients With Unstable Angina/Non ST-Elevation Myocardial Infarction:

Circulation 116: 803 - 877, 2007

5 The American College of Cardiology/The American Heart Association/The Society of Cardiovascular Angiography and Interventions

6 ACC/AHA/SCAI 2005 Guideline Update for Percutaneous Coronary Intervention:

Circulation 113(7): e166 - e286, 2006

7 The European Society of Cardiology

8 Guidelines for the diagnosis and treatment of non-ST-segment elevation acute coronary syndromes: Eur Heart J. 28(13):1598-1660, 2007