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# FDA APPROVES NEW 300MG LOADING DOSE TABLET FOR PLAVIX® (clopidogrel bisulfate)

- May Help Increase Appropriate Early Use in Acute Coronary Syndrome Patients -

(BRIDGEWATER, NJ and PRINCETON, NJ, September 27, 2007) – Sanofi-aventis (EURONEXT: SAN and NYSE: SNY) and Bristol-Myers Squibb Company (NYSE: BMY) announced today that the U.S. Food and Drug Administration (FDA) has approved a supplemental new drug application (sNDA) for a 300mg tablet of the antiplatelet PLAVIX® (clopidogrel bisulfate). The PLAVIX 300mg tablet will facilitate the use of the FDA approved loading dose for appropriate acute coronary syndrome (ACS) patients as soon as possible after hospital admission. Acute ST-segment elevation myocardial infarction (STEMI), along with unstable angina (UA) and non-ST segment elevation myocardial infarction (NSTEMI), are the three conditions classified as ACS, a major cause of emergency medical care and hospitalization in the United States.

"The American College of Cardiology-American Heart Association treatment guidelines for UA/NSTEMI and the American Heart Association Cardiopulmonary Resuscitation and Emergency Cardiac Care guidelines for ACS patients (August 2007) recommend a 300mg loading dose of clopidogrel in conjunction with ASA (aspirin), yet many appropriate ACS patients do not receive a loading dose of clopidogrel," said Dr. Marc Cohen, F.A.C.C., Chief of the Division of Cardiology, and Director of the Cardiology fellowship at the Newark Beth Israel Medical Center and Professor of Medicine at the Mount Sinai School of Medicine.

"The 300mg loading dose has been proven effective in a broad ACS patient population," said Cohen. "A broad ACS population includes not only UA and NSTEMI, but also STEMI as supported by CURE, CLARITY and COMMIT trials."

The 300mg tablet is bioequivalent to four 75mg FDA approved tablets of PLAVIX. The 300mg tablet of clopidogrel will be available in the U.S. later this year and is also currently under European Medicines Evaluation Agency (EMEA) review.

### **About PLAVIX**

PLAVIX is a prescription antiplatelet medicine taken once a day that helps keep platelets in the blood from sticking together and forming clots. Since its initial approval on November 17, 1997, by the U.S. Food and Drug Administration, PLAVIX has been prescribed to more than 52 million patients worldwide. The new 300mg loading dose tablet reinforces the strong commitment of two research and development pharmaceutical companies dedicated to improving patient health.

The efficacy and safety of PLAVIX have been established through four landmark clinical trials involving more than 81,000 patients. Plavix is the only widely available prescription antiplatelet that provides proven protection against a future heart attack or stroke for patients with ACS (UA, NSTEMI, STEMI) and recent MI, recent Stroke, or established peripheral artery disease.

PLAVIX has demonstrated early and long-term risk reduction for patients at risk for atherothrombotic events in important clinical trials. In the CURE trial, patients with unstable angina (UA) and non-ST segment elevation myocardial infarction (NSTEMI) receiving PLAVIX with aspirin were followed for up to one year, and in the CAPRIE trial, patients with recent MI, recent ischemic stroke, or established peripheral artery disease receiving PLAVIX alone were followed for up to three years.

PLAVIX is marketed worldwide by sanofi-aventis (Paris Bourse: EURONEXT: SAN; New York: NYSE: SNY) and Bristol-Myers Squibb Company (NYSE: BMY) as Plavix<sup>®</sup> and Iscover<sup>®</sup>.

If you have a stomach ulcer or other condition that causes bleeding, you should not use Plavix. When taking Plavix alone or with some other medicines including aspirin, the risk of bleeding may increase so tell your doctor before planning surgery. And, always talk to your doctor before taking aspirin or other medicines with Plavix, especially if you've had a stroke. If you develop fever, unexplained weakness or confusion, tell your doctor promptly as these may be signs of a rare but potentially life-threatening condition called TTP, which has been reported rarely, sometimes in less than 2 weeks after starting therapy. Other rare but serious side effects may occur.

For more information on PLAVIX visit <u>www.plavix.com</u>.

# WHO SHOULD RECEIVE Plavix (clopidogrel bisulfate)?

PLAVIX is indicated for the reduction of atherothrombotic events as follows:

# • Recent Myocardial Infarction (MI), Recent Stroke, or Established Peripheral Arterial Disease (PAD)

For patients with a history of recent MI, recent stroke, or established PAD, PLAVIX has been shown to reduce the rate of a combined end point of new ischemic stroke (fatal or not), new MI (fatal or not), and other vascular death.

## • Acute Coronary Syndrome (ACS)

For patients with non-ST-segment elevation ACS (unstable angina/non–Q-wave MI), including patients who are to be managed medically and those who are to be managed with percutaneous coronary intervention (with or without stent) or coronary artery bypass graft surgery (CABG), PLAVIX has been shown to decrease the rate of a combined end point of cardiovascular death, MI, or stroke as well as the rate of a combined end point of cardiovascular death, MI, stroke, or refractory ischemia.

For patients with ST-segment elevation acute myocardial infarction, PLAVIX has been shown to reduce the rate of death from any cause and the rate of a combined endpoint of death, reinfarction or stroke. This benefit is not known to pertain to patients who receive primary angioplasty.

# **Important Risk Information**

- PLAVIX is contraindicated in patients with active pathologic bleeding such as peptic ulcer or
  intracranial hemorrhage. PLAVIX should be used with caution in patients who may be at risk
  of increased bleeding from trauma, surgery, or coadministration with NSAIDs or warfarin. (See
  CONTRAINDICATIONS and PRECAUTIONS.\*)
- The rates of major and minor bleeding were higher in patients treated with PLAVIX plus aspirin compared with placebo plus aspirin in clinical trials. (See ADVERSE REACTIONS.\*)
- As part of the worldwide post marketing experience with PLAVIX, there have been cases of reported thrombotic thrombocytopenic purpura (TTP), some with fatal outcome. TTP has been reported rarely following use of PLAVIX, sometimes after a short exposure (<2 weeks). TTP is a serious condition that can be fatal and requires urgent treatment including plasmapheresis (plasma exchange). (See WARNINGS.\*)</li>
- In clinical trials, the most common clinically important side effects were pruritus, purpura, diarrhea, and rash; infrequent events included intracranial hemorrhage (0.4%) and severe neutropenia (0.05%). (See ADVERSE REACTIONS.\*)

\*Please see full prescribing information by visiting www.plavix.com.

### **About sanofi-aventis**

Sanofi-aventis is one of the world leaders in the pharmaceutical industry, 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, thrombosis, oncology, metabolic

diseases, central nervous system, internal medicine and vaccines. Sanofi-aventis is listed in Paris (EURONEXT: SAN) and in New York (NYSE: SNY).

# **About Bristol-Myers Squibb**

Bristol-Myers Squibb is a global pharmaceutical and related health care products company whose mission is to extend and enhance human life.