Powerful New Efficacy Data in Moderate and Severe Hypertensive Patients Supports FDA Approval of AVALIDE® as the First Combination Therapy for Initial Use in Patients Likely to Need Multiple Drugs to Achieve Their Blood Pressure Goals

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AVALIDE demonstrated powerful mean blood pressure reductions of 30.8 mm Hg systolic blood pressure (SBP) and 24.0 mm Hg diastolic blood pressure (DBP) at five weeks and 21.1/19.3 mm Hg (SBP/DBP) for irbesartan alone in a study of patients with severe hypertension

AVALIDE also demonstrated mean BP reductions of 27.1/14.6 mm Hg (SBP/DBP) at 8 weeks, and 22.1/11.6 mm Hg and 15.7/7.3 mm Hg (SBP/DBP) reductions respectively for irbesartan and HCTZ alone, in a study of patients with moderate hypertension

PARIS & PRINCETON, N.J.--(BUSINESS WIRE)--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 the supplemental new drug application (sNDA) for the antihypertensive agent AVALIDE® (irbesartan-hydrochlorothiazide) for initial use in patients with hypertension who are likely to need multiple drugs to achieve their blood pressure goals.

The approval is based on data from two clinical trials involving more than 1,200 patients with moderate or severe high blood pressure.

In the first double-blind, active-controlled, seven-week trial, patients with severe hypertension (mean baseline 172/113 mm Hg SBP/DBP) were randomly treated with either AVALIDE 150/12.5 mg (n=468) or irbesartan 150 mg monotherapy (n=227). After one week, all doses were doubled. At five weeks, AVALIDE® (irbesartan-hydrochlorothiazide) 300/25 mg demonstrated mean blood pressure reductions of 30.8/24.0 mm Hg versus 21.1/19.3 mm Hg (SBP/DBP) for irbesartan 300 mg alone (P<.0001).

In the second double-blind, active-controlled, 12-week trial, patients with moderate hypertension (mean baseline 162/98 mm Hg SBP/DBP) were randomly treated with AVALIDE 150/12.5 mg (n=328), irbesartan 150 mg monotherapy (n=106), or hydrochlorothiazide 12.5 mg monotherapy (n=104). After two weeks, all doses were doubled. The primary endpoint was mean change in SBP from baseline to Week 8. At eight weeks, AVALIDE 300/25 mg demonstrated mean blood pressure reductions of 27.1/14.6 mm Hg (SBP/DBP), which was significantly greater than irbesartan 300 mg or hydrochlorothiazide 25 mg alone, 22.1/11.6 mm Hg (P<.01) and 15.7/7.3 mm Hg (P<.0001) (SBP/DBP), respectively.

In the severe hypertension study, the incidences of pre-specified adverse events on AVALIDE vs. irbesartan were: syncope (0% vs. 0%), hypotension (0.6% vs. 0%), dizziness (3.6% vs. 4.0%), headache (4.3% vs. 6.6%), hyperkalemia (0.2% vs. 0%), and hypokalemia (0.6% vs. 0.4%). In the moderate hypertension study, the incidences of pre-specified adverse events on AVALIDE vs. irbesartan or hydrochlorothiazide monotherapy were: hypotension (0.9% vs. 0% and 0%), dizziness (3.0% vs. 3.8% and 1.0%), headache (5.5% vs. 3.8% and 4.8%), hyperkalemia (1.2% vs. 0% and 1.0%), and hypokalemia (0.9% vs. 0% and 0%).

“Guidelines support initial combination therapy for severe hypertension based on the need to lower BP within weeks rather than months,” said Dr. Joel Neutel, Professor of Medicine, University of California in Irvine.

“Now with AVAPRO® (irbesartan) and AVALIDE physicians have more therapeutic options to treat mild, moderate and severe hypertension,” added Dr. Neutel.

AVAPRO is indicated for the treatment of hypertension and also helps to slow the progression of nephropathy in type 2 diabetic hypertensive patients. AVALIDE may be used in appropriate patients whose blood pressure is not adeqately
controlled on monotherapy and now can be used as initial therapy in appropriate patients who are likely to need multiple drugs to achieve their blood pressure goals.

"JNC 7 guidelines recommend that physicians consider starting with combination therapy for most patients with stage 2 hypertension," said Dr. Michael Weber, Professor of Medicine, SUNY Downstate College of Medicine. "In addition, the approval of AVALIDE® (irbesartan-hydrochlorothiazide) as a first-line therapy in patients likely to need multiple drugs to achieve their blood pressure goals provides physicians with an FDA-approved therapeutic option in one tablet."

ABOUT AVAPRO® (irbesartan) and AVALIDE

In the United States, AVAPRO is indicated for the treatment of hypertension. It may be used alone or in combination with other antihypertensive agents.

AVAPRO is also indicated for the treatment of diabetic nephropathy with an elevated serum creatinine and proteinuria (≥300 mg/day) in patients with type 2 diabetes and hypertension. In this population, AVAPRO reduces the rate of progression of nephropathy as measured by the occurrence of doubling of serum creatinine or end-stage renal disease (need for dialysis or renal transplantation).

AVALIDE is a fixed-dose combination of the angiotensin II receptor blocker (ARB) AVAPRO and a diuretic (hydrochlorothiazide).

AVALIDE is indicated for the treatment of hypertension.

AVALIDE may be used in patients whose blood pressure is not adequately controlled on monotherapy.

AVALIDE may also be used as initial therapy in patients who are likely to need multiple drugs to achieve their blood pressure goals.

The choice of AVALIDE as initial therapy for hypertension should be based on an assessment of potential benefits and risks.

IMPORTANT SAFETY INFORMATION

-- Because of the hydrochlorothiazide component, AVALIDE® (irbesartan-hydrochlorothiazide) is contraindicated in patients with anuria or hypersensitivity to sulfonamide-derived drugs

-- In patients with volume or sodium depletion (eg, patients vigorously treated with diuretics or on dialysis), such depletion should be corrected prior to administration of AVAPRO® (irbesartan) or AVALIDE, or a lower initial dose of AVAPRO (75 mg) should be used, to avoid possible symptomatic hypotension

-- Hypersensitivity reactions to hydrochlorothiazide may occur in patients with or without a history of allergy or bronchial asthma, but are more likely in patients with such a history

-- Thiazide diuretics have been reported to cause exacerbation or activation of systemic lupus erythematosus

-- Lithium generally should not be given with thiazides

-- Thiazides should be used with caution in patients with severe renal disease and in patients with impaired hepatic function or progressive liver disease, since minor alterations of fluid and electrolyte balance may precipitate hepatic coma

-- In placebo-controlled hypertension studies, there were no significant differences in adverse events (AEs) between AVAPRO and placebo. Adverse events that occurred in at least 1% of patients treated with AVAPRO and at a higher incidence vs placebo included diarrhea (3% vs 2%), dyspepsia/heartburn (2% vs 1%) and fatigue (4% vs 3%)

-- Additionally, in a study of hypertensive type 2 diabetic patients with renal disease (proteinuria ≥ 900 mg/day), the reported AEs for AVAPRO were similar to those seen in hypertension studies, with the exception of an increased incidence of orthostatic symptoms; AVAPRO compared to placebo (both groups received adjunctive antihypertensives): dizziness (10.2% vs 6.0%), orthostatic dizziness (5.4% vs 2.7%) and orthostatic hypotension (5.4% vs 3.2%), respectively. In patients with proteinuria, monitor serum potassium

-- In placebo-controlled hypertension studies, the most common adverse experiences reported with AVALIDE that occurred in ≥1% of patients and at a higher incidence vs placebo included fatigue (7% vs 3%), musculoskeletal pain (7% vs 5%), dizziness (8% vs 4%), and nausea/vomiting (3% vs 0%). Additionally, in studies of moderate and severe hypertension where AVALIDE was used as initial therapy, the types and incidences of adverse events reported for AVALIDE were similar to monotherapy

About sanofi-aventis

Sanofi-aventis is 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).

About Bristol-Myers Squibb

Bristol-Myers Squibb is a global pharmaceutical and healthcare products company whose mission is to extend and enhance human life. Visit Bristol-Myers Squibb at http://www.bms.com.

Forward Looking

For sanofi-aventis

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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 risks that may arise from the outcome of any appeal, the adverse impact of generic product distributed into the market by Apotex, the potential launch of a generic clopidogrel bisulfate product by other entities, as well as 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, 2006. Other than as required by applicable law, sanofi-aventis does not undertake any obligation to update or revise any forward-looking information or statements.

For Bristol-Myers Squibb

This press release contains “forward-looking statements” as that term is defined in the Private Securities Litigation Reform Act of 1995. Such forward-looking statements are based on current expectations and involve inherent risks and uncertainties, including factors that could delay, divert or change any of them, and could cause actual outcomes and results to differ materially from current expectations. No forward-looking statement can be guaranteed. Forward-looking statements in this press release should be evaluated together with the many uncertainties that affect Bristol-Myers Squibb’s business, particularly those identified in the cautionary factors discussion in Bristol-Myers Squibb’s Annual Report on Form 10-K for the year ended December 31, 2006, in our Quarterly Reports on Form 10-Q and our Current Reports on Form 8-K. Bristol-Myers Squibb undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise.

For full Prescribing Information including boxed WARNING regarding Use in Pregnancy, please visit: http://www.AVAPROAVALIDE.com or http://www.bms.com.

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