New Drug Provides One-Two Punch Against High Blood Pressure

(NAPSA)—Did you know that one in three Americans has high blood pressure? Are you one of them? You won't know unless you get your blood pressure checked—and you should, because high blood pressure puts you at higher risk for cardiovascular disease.

You need to get your blood pressure checked regularly, even if you don't have high blood pressure right now, as there are often no outwardly recognizable symptoms. Because of this, many people don't even know they have it until the damage is already done, and uncontrolled high blood pressure can lead to serious health problems such as stroke, heart attack, heart failure or kidney failure.

If you have high blood pressure, like many others, you may need more than one medication to control it. If you do, you may want to ask your doctor about taking a single pill. There are options that offer two prescription medications in one—the newest is called Twynsta® (telmisartan/amlodipine) Tablets, and you take it just once a day.

The prescription medication was recently approved by the U.S. Food and Drug Administration (FDA) for the treatment of high blood pressure, alone or in combination with other blood pressure–lowering drugs. TWYNSTA provides a new option for people whose high blood pressure is not controlled with an angiotensin II receptor blocker or calcium channel blocker alone, or those who may need to take multiple medications to reach their blood pressure goals. People taking TWYNSTA in clinical studies also experienced less swelling at certain dosages than those taking the calcium channel blocker amlodipine alone, specifically swelling or puffiness that is most commonly noticed in the feet, ankles and legs.

All medications have risks as well as benefits, and it is not clear why some medications cause side effects in some patients but not others. If you are one of those who do experience side effects, you need to talk with your doctor to find the right treatment for you.

TWYNSTA is not for pregnant women. Taking TWYNSTA during pregnancy can cause injury and even death to an unborn baby. If you get pregnant, stop taking TWYNSTA and call your doctor right away. If you plan to become pregnant or breast-feed, talk to a doctor about other ways to lower your blood pressure. Other possible serious side effects with TWYNSTA include low blood pressure, kidney problems, heart problems or heart attack. Other rare but serious side effects may occur. Before taking TWYNSTA, tell your doctor about any medical conditions you have, including any liver, kidney or heart problems, and about all other medications you are taking.

For full Prescribing Information with Boxed Warning for TWYNSTA, please contact Boehringer Ingelheim Pharmaceuticals, Inc. Drug Information Unit at (800) 542-6257, option #4.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call (800) FDA-1088.

Editors' Note:

About Twynsta® (telmisartan/amlodipine) Tablets

Telmisartan/amlodipine is marketed in the U.S. as TWYNSTA Tablets by Boehringer Ingelheim Pharmaceuticals, Inc.

TWYNSTA is indicated for the treatment of hypertension, alone or with other antihypertensive agents. It may also be used as initial therapy in patients who are likely to need multiple drugs to achieve their blood pressure goals.

WARNING: AVOID USE IN PREGNANCY

When used in pregnancy, drugs that act directly on the renin-angiotensin system can cause injury and even death to the developing fetus. When pregnancy is detected, TWYNSTA should be discontinued as soon as possible [see Warnings and Precautions].

In patients with an activated renin-angiotensin system, such as volume- and/or salt-depleted patients, symptomatic hypotension may occur after initiation of therapy with TWYNSTA Tablets. This condition should be corrected prior to administration of TWYNSTA Tablets, or treatment should start under close medical supervision with a reduced dose.

Since the vasodilation induced by amlodipine in TWYNSTA is gradual in onset, acute hypotension has rarely been reported after oral administration. Nonetheless, caution, as with any other peripheral vasodilator, should be exercised when administering amlodipine, particularly in patients with severe aortic stenosis.

As the majority of telmisartan is eliminated by biliary excretion, patients with biliary obstructive disorders or hepatic insufficiency can be expected to have reduced clearance. TWYNSTA should be used with caution in these patients.

Since amlodipine is extensively metabolized by the liver and the plasma elimination half-life (t1/2) is 56 hours in patients with impaired hepatic function, caution should be exercised when administering TWYNSTA to patients with severe hepatic impairment.

In patients whose renal function may depend on the activity of the renin-angiotensin-aldosterone system (e.g., patients with severe CHF), treatment with angiotensin-converting enzyme inhibitors and angiotensin receptor antagonists has been associated with oliguria and/or progressive azotemia and (rarely) with acute renal failure and/or death. Similar results may be anticipated in patients treated with TWYNSTA Tablets.

In studies of ACE inhibitors in patients with renal artery stenosis, increases in serum creatinine or blood urea nitrogen were observed. An effect similar to that seen with ACE inhibitors should be anticipated with TWYNSTA Tablets.

Dual blockade of the renin-angiotensin-aldosterone system (e.g., by adding an ACE-inhibitor to an angiotensin II receptor antagonist) should be used with caution and should include close monitoring of renal function. Concomitant use of telmisartan and ramipril is not recommended.

Patients, particularly those with severe obstructive coronary artery disease, may develop increased frequency, duration or severity of angina or acute myocardial infarction on starting calcium channel blocker therapy or at the time of dosage increase.

Closely monitor patients with heart failure.

In the placebo-controlled factorial design study, the most common reasons for discontinuation of therapy with TWYNSTA Tablets were peripheral edema, dizziness, and hypotension, each leading to discontinuation of ≤0.5% of TWYNSTA-treated patients. Adverse reactions that occurred at a ≥2% higher incidence on TWYNSTA Tablets than placebo were peripheral edema (4.8% vs 0%), dizziness (3.0% vs 2.2%), clinically meaningful orthostatic hypotension (6.3% vs 4.3%), and back pain (2.2% vs 0%).

In clinical studies, the magnitude of blood pressure lowering with TWYNSTA in black patients approached that observed in non-black patients, but the number of black patients was limited.

In patients who are 75 years or hepatically impaired, amlodipine should usually be started or added at a dose of 2.5mg.

In nursing mothers, nursing or TWYNSTA should be discontinued.

For more information about TWYNSTA or to receive a package insert please contact Boehringer Ingelheim Pharmaceuticals, Inc. Drug Information Unit at (800) 542-6257, option #4.