New Treatment Approved For Black Heart Failure Patients

(NAPSA)—There may be good news for thousands of black patients suffering from heart failure, a disease that affects this community at a higher rate than other U.S. populations. The U.S. Food and Drug Administration recently approved BiDil® (isosorbide dinitrate/hydralazine hydrochloride) as an adjunct to current standard heart failure therapy in self-identified black patients.

Heart failure is a progressively worsening condition that occurs when the heart muscle weakens and cannot pump blood efficiently enough to meet the needs of the body. According to the Centers for Disease Control and Prevention, African Americans between the ages of 45 and 64 are 2.5 times more likely to die from heart failure than Caucasians in the same age range.

"The devastating effect of heart failure in African Americans warrants the medical community's attention," said Clyde Yancy, M.D., University of Texas Southwestern Medical Center at Dallas. "The approval of BiDil is a landmark occasion and the benefits seen in the patients taking the drug will help tackle the disproportionate burden suffered by this community."

The approval of BiDil was based primarily on results from the African American Heart Failure Trial (A-HeFT). Cosponsored by NitroMed and the Association of Black Cardiologists, A-HeFT was the first clinical trial conducted in an all black heart failure patient population.

In the trial, those patients taking BiDil in addition to their current standard heart failure therapies experienced an improvement in survival, a decrease in the rate of first hospitalizations for heart failure and an improvement in their self-reported functional status, when compared to patients receiving a variety of current heart failure therapies plus placebo.

"After the trial I was able to return to many of the things I did before being diagnosed with heart failure," said Leland Ramey, an A-HeFT patient from Cincinnati, Ohio. "I now have the energy to spend more quality time with my family."

To learn more about heart failure and BiDil, consult your physician and visit www.bidil.com.

Editor's Note: Headache (50%) and dizziness (32%) were the two most frequent adverse events and were more than twice as frequent in the patients taking BiDil. Patient experiences may vary.

INDICATIONS

BiDil is indicated for the treatment of heart failure as an adjunct to current standard heart failure therapy in self-identified black patients to improve survival, prolong time to hospitalization for heart failure and improve patient-reported functional status. There is little experience in patients with New York Heart Association (NYHA) class IV heart failure. Most patients in the clinical trial supporting effectiveness, referred to as the African American Heart Failure Trial (A-HeFT), received, in addition to BiDil or placebo, a loop diuretic, an angiotensin converting enzyme inhibitor or an angiotensin II receptor blocker, and a beta blocker, and many also received a cardiac glycoside or an aldosterone antagonist.

IMPORTANT SAFETY INFORMATION

Augmentation of the vasodilatory effects of isosorbide dinitrate by phosphodiesterase inhibitors (e.g., Viagra®/Revatio™, Levitra®, Cialis®) could result in severe hypotension.

Treatment with hydralazine may produce a clinical picture simulating systemic lupus erythematosus (SLE) including glomerulonephritis. If SLE-like symptoms occur, discontinuation of BiDil should be considered. Residua have been detected many years after discontinuation of hydralazine.

Symptomatic hypotension may occur with even small doses of BiDil. BiDil should be used with caution in volume-depleted or hypotensive patients.

Hydralazine can cause tachycardia potentially leading to myocardial ischemia and anginal attacks.

Caution should be exercised if BiDil is used with MAO inhibitors, alcohol, sildenafil, vardenafil or tadalafil.

Headache (50%) and dizziness (32%) were the two most frequent adverse events and were more than twice as frequent in the BiDil group.

Viagra is a registered trademark and Revatio is a trademark of Pfizer, Inc.; Levitra is a registered trademark of Bayer Heathcare, GlaxoSmithKline, and Schering-Plough; Cialis is a registered trademark of Lilly ICOS LLC.

For complete prescribing information for BiDil, visit www.BiDil.com.