

**FDA ACCEPTS NITROMED'S NEW DRUG APPLICATION RESUBMISSION FOR BiDil®**  
*Submission Granted a June 23, 2005 PDUFA Date*

**LEXINGTON, Mass. February 3, 2005** — NitroMed, Inc. (NASDAQ: NTMD) announced today that the U.S. Food and Drug Administration (FDA) has accepted the resubmission of the New Drug Application (NDA) for BiDil® (a fixed combination of isosorbide dinitrate and hydralazine) as a complete, Class 2 resubmission. BiDil is the first heart failure treatment tested in an all African American patient population and recently demonstrated a 43% survival benefit for African Americans in a phase III study. Under the Prescription Drug User Fee Act (PDUFA), FDA review of a Class 2 resubmission is expected to be completed within a six-month period, beginning on the date that the resubmission was received. The PDUFA date for the BiDil NDA is June 23, 2005.

"This is an important step in NitroMed's regulatory process for achieving our goal of bringing BiDil to a community disproportionately burdened by heart failure," said Manuel Worcel, M.D., Chief Medical Officer for NitroMed. "While acceptance of the BiDil NDA resubmission does not ensure FDA approval, we believe that our clinical data demonstrate a significant benefit for African American heart failure patients."

The African American Heart Failure Trial (A-HeFT), a phase III study testing BiDil, was co-sponsored by NitroMed and the Association of Black Cardiologists (ABC). A-HeFT, the first trial ever conducted in an all African American heart failure patient population, enrolled 1,050 patients in a double-blind, placebo-controlled study at 169 clinical research sites. In July 2004, A-HeFT was halted early due to the significant survival benefit seen in patients on BiDil.

A-HeFT results demonstrated that African American patients with heart failure experienced a 43% improvement in survival, a 33% reduction in first hospitalization for heart failure and an improvement in quality of life after taking BiDil. Adverse events reported in the trial included symptoms of headache and dizziness, which were significantly more frequent in the group given BiDil, and exacerbations of congestive heart failure (both moderate and severe), which were significantly more frequent in the placebo group. These results, which occurred with BiDil added to standard heart failure therapy, were presented at the American Heart Association's Scientific Sessions in November 2004 and were published in the *New England Journal of Medicine*.

**Heart Failure Prevalence in African Americans**

Heart failure, or end-stage cardiovascular disease, affects approximately five million Americans. There is no cure for this disease, and more than 50 percent of patients die within five years of diagnosis. The African American community is affected at a greater frequency by heart failure than the corresponding Caucasian population. 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.

**About BiDil**

As the lead product in development for NitroMed, BiDil is an orally-administered nitric oxide-enhancing drug candidate that was investigated in A-HeFT for its potential, when administered together with standard heart failure therapies, to reduce mortality and hospitalization and improve the quality of life of African Americans diagnosed with heart failure. BiDil is a combination of two drugs, isosorbide dinitrate and hydralazine. Isosorbide dinitrate is a nitric oxide donor. Hydralazine is an antioxidant and vasodilator, which means that it protects nitric oxide formed by isosorbide dinitrate and dilates blood vessels. Neither drug separately is indicated for heart failure. Because heart failure is a chronic disease, if approved, BiDil, like other medicines taken for chronic heart disease, will be taken for the duration of the patient's life.

**About NitroMed, Inc.**

NitroMed is an emerging pharmaceutical company focused on the research, development and

commercialization of proprietary pharmaceuticals based on the therapeutic benefits of the naturally occurring molecule nitric oxide. The Company uses its expertise in nitric oxide biology and chemistry in an effort to develop both new pharmaceuticals, as well as safer, more effective versions of existing drugs. Research and development efforts focus on major diseases that are characterized by a deficiency in nitric oxide, such as cardiovascular and inflammatory diseases. BiDil, the Company's lead product candidate, is an orally administered nitric oxide-enhancing medicine being developed for the treatment of heart failure in African Americans. Corporate collaborations are also an element of the Company's business strategy, and NitroMed has an agreement with Boston Scientific to jointly develop nitric oxide-enhanced cardiovascular stents.

### **Forward Looking Statements**

Any statements in this press release about future expectations, plans and prospects for the Company, including statements regarding the expected benefit of BiDil for African American heart failure patients, as well as statements containing the words "believe," "anticipate," "plan," "expect," "will," "may," and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including risks relating to: difficulties or delays relating to required regulatory approvals to market and sell BiDil and to develop, market and sell the Company's other products under development; the Company's ability to develop or successfully contract for the sales, marketing and manufacturing competencies required to launch BiDil and any other product candidates for which it may receive regulatory approval; the Company's ability to successfully complete clinical trials of its products under development; the Company's dependence on corporate collaborators to develop, manufacture, market and sell products based upon its technologies; the Company's failure to obtain or maintain intellectual property protection and required licenses for its technologies and products under development; the Company's ability to obtain the substantial additional funding required to conduct research and development, manufacturing, marketing and sales of its products under development; and other factors discussed in its Quarterly Report on Form 10-Q for the quarter ended September 30, 2004, which is filed with the SEC. In addition, the forward-looking statements included in this press release represent the Company's views as of the date of this release. The Company anticipates that subsequent events and developments will cause the Company's views to change. However, while the Company may elect to update these forward-looking statements at some point in the future, the Company specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing the Company's views as of any date subsequent to the date of this release.

"Safe Harbor" Statement under the Private Securities Litigation Reform Act of 1995: Statements in this press release regarding NitroMed, Inc.'s business which are not historical facts are "forward-looking statements" that involve risks and uncertainties. For a discussion of such risks and uncertainties, which could cause actual results to differ from those contained in the forward-looking statements, see "Risk Factors" in the Company's Annual Report or Form 10-K for the most recently ended fiscal year.