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Bucindolol Significantly Reduces Hospitalization and Death in Heart Failure Patients with Very Favorable Genotypes

Common Genetic Variations Predict Patient Response to Novel Beta Blocker Therapy

Toronto – September 22, 2008 – Bucindolol, an investigational, pharmacologically unique beta-blocker and mild vasodilator, significantly reduces hospitalization and death among heart failure patients with very favorable genotypes, according to results of a large DNA study presented today as a poster at the annual meeting of the Heart Failure Society of America. Researchers found that common genetic variations can predict which heart failure patients will have the greatest therapeutic response to bucindolol.

“The ability to predict patient response to bucindolol makes it easier for physicians to match the right patient to the right medicine, potentially avoiding months of trial-and-error therapy and helping very sick heart failure patients achieve better outcomes sooner,” said Christopher O’Connor, M.D., Director of the Heart Center at Duke University Medical Center and presenter of the study. “This data brings us much closer to realizing the benefits of personalized medicine in heart failure.”

The prospectively-designed DNA sub-study included more than 1,000 patients enrolled in the Beta-Blocker Evaluation of Survival Trial (BEST), the largest heart failure mortality trial conducted primarily in the United States. Researchers evaluated therapeutic response to bucindolol among patients with genetic variations, or polymorphisms, in two adrenergic receptors that help regulate cardiac function: β_1 389 Arg/Gly and α_{2c} 322-325 WT/Del. Researchers identified three distinct genotypes that predict the effect of bucindolol: very favorable (47% of BEST patients), favorable (40%) and unfavorable (13%).

In the study, patients with the very favorable genotype experienced the following compared to placebo:

- 38 percent reduction in all cause mortality ($p < 0.05$)
- 43 percent reduction in all cause mortality or transplant ($p < 0.05$)
- 48 percent reduction in cardiovascular mortality ($p < 0.05$)
- 44 percent reduction in heart failure hospitalization ($p < 0.01$)
- 36 percent reduction in cardiovascular hospitalization ($p < 0.01$)

While the most robust clinical effects occur with the very favorable genotype group, patients with the favorable genotype also benefit from treatment with bucindolol. Bucindolol also demonstrated clinically significant improvements in ischemic endpoints including reducing the risk of myocardial infarction.

“Bucindolol offers physicians a tremendous advantage to predict response,” said William Abraham, M.D., Director of Cardiovascular Medicine at the Ohio State University Medical Center. “This is vitally important since the annual mortality rate for heart failure patients can be as high as 20 percent. With these patients, we have no time to spare.”

Michael Bristow, M.D., Chairman and Chief Science and Medical Officer of ARCA biopharma, said, “While currently available beta blockers are a mainstay in medicine, it is difficult for physicians to predict which patients will respond to which therapy. Bucindolol interacts with certain polymorphism of adrenergic receptors that help regulate cardiac function, allowing us to predict patient clinical response using a simple genetic test. The time is coming when we can realize the benefits of personalized medicine in cardiovascular disease.”

About Beta Blockers

The use of beta blockers is the standard of care in patients with heart failure and left ventricular dysfunction, according to clinical practice guidelines of the American Heart Association, the American College of Cardiology and the Heart Failure Society of America. HFSA guidelines state: “Beta-blocker therapy remains a major advance in the treatment of patients with LV systolic dysfunction. Along with ACE inhibitors, this class of drug is now established as routine therapy in patients with LV systolic dysfunction.”

About Heart Failure

Heart failure is a chronic and progressive condition in which the heart cannot efficiently pump blood to meet the body’s oxygen demands. The American Heart Association (AHA) estimates that about 6 million Americans are living with heart failure, with 550,000 new cases diagnosed annually, Heart failure accounts directly for 55,000 deaths and indirectly for an additional 230,000 deaths in the United States each year. Heart failure is the underlying reason for approximately 12 to 15 million annual visits to physicians and 6.5 million annual hospital days.

About ARCA biopharma

ARCA biopharma, Inc. is a privately held company focused on developing and commercializing genetically targeted therapies for heart failure and other cardiovascular diseases. The Company’s lead product, bucindolol, is an investigational, pharmacologically unique beta-blocker and mild vasodilator being developed for heart failure and other indications. ARCA has identified common genetic variations that predict individual patient response to bucindolol. ARCA, in partnership with Laboratory Corporation of America, is developing a companion genetic test for bucindolol. For more information please visit www.arcabiopharma.com.

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