



Contact:

Rebekah Brooks
Invigorate Communications
312-282-9435
rbrooks@invigoratepr.com

FDA Accepts New Drug Application for Bucindolol, A Genetically-Targeted Treatment for Heart Failure from ARCA biopharma

Broomfield, Colo., Sept. 23, 2008 – ARCA biopharma, Inc. announced today that the U.S. Food and Drug Administration (FDA) has accepted a New Drug Application (NDA) for the company’s lead product candidate, bucindolol, an investigational and pharmacologically unique beta-blocker and mild vasodilator developed for the treatment of chronic heart failure. If approved by the FDA, bucindolol could become the first genetically targeted cardiovascular therapy.

Bucindolol significantly reduces both hospitalizations and deaths in heart failure patients with a specific, common genetic variation compared to placebo, according to results from a prospectively defined genetic sub-study of the Beta Blocker Evaluation of Survival Trial (BEST), a large Phase III clinical trial funded and conducted by the National Institutes of Health and the Veterans Affairs Cooperative. This data was presented this week by Christopher O’Connor, M.D., director of the Heart Center at Duke University Medical Center, at the Heart Failure Society of America (HFSA) annual meeting in Toronto.

“Bucindolol has the potential to become an important new treatment for heart failure. Clinical responses to bucindolol are substantially enhanced when administered to genetically targeted heart failure populations,” said Michael R. Bristow, M.D., chairman, chief science and medical officer, and founder of ARCA biopharma. “This makes it possible for physicians to personalize treatment with the goal of improving patient outcomes, reducing hospitalization and avoiding the ‘trial and error’ process that is common in treating heart failure patients today.”

Dr. Bristow, along with Stephen Liggett, M.D. of the University of Maryland, conducted genetic research to identify heart failure patients who are most likely to respond to bucindolol therapy. This genetic subgroup constitutes approximately 50 percent of the U.S. heart failure population.

“By seeking regulatory approval for bucindolol, we are taking a major step forward in our quest to bring the benefits of personalized medicine to cardiovascular disease,” said Richard B. Brewer, president and chief executive officer of ARCA biopharma. “We look forward to working with the FDA to make bucindolol available to physicians and patients. We are also working with our partner, LabCorp of America, to develop and introduce a companion genetic test.”

In the genetic sub-study of the BEST trial, researchers categorized patients into three groups based on receptor genotype: very favorable, favorable and unfavorable. Patients with the very favorable genotype experienced significant improvements in clinical endpoints compared to placebo, including reductions in all cause mortality, all cause mortality or transplant, cardiovascular mortality, heart failure hospitalization, and cardiovascular hospitalization. While the most robust clinical effects occurred in the very favorable genotype group, patients with the favorable genotype also benefitted from treatment with bucindolol. Bucindolol also demonstrated clinically significant improvements in ischemic endpoints including reducing the risk of myocardial infarction.

Patients with the unfavorable genotype, approximately 10 percent of the study population, did not respond to bucindolol therapy.

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 Heart Failure Society of America (HFSA), the American Heart Association, and the American College of Cardiology. 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 estimates that about six 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, Gencaro™ (bucindolol hydrochloride)*, is an investigational, pharmacologically unique beta-blocker and mild vasodilator being developed for heart failure and other indications. ARCA biopharma, in partnership with Laboratory Corporation of America (NYSE:LH), is developing a companion genetic test for bucindolol. For more information please visit www.arcabiopharma.com.

** The tradename Gencaro™ is currently pending regulatory including FDA approval.*

###