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Data from Gencaro™ Phase 3 Best Trial Presented at the American College of Cardiology 58th Annual Scientific Session

Results of 2,700-Patient Trial Show Benefit of Gencaro, a Genetically-Targeted Beta Blocker, in Moderate to Severe Heart Failure Patients

ACC.09 Annual Scientific Session Exposition

BROOMFIELD, Colo.--([BUSINESS WIRE](#))--ARCA biopharma, Inc. (Nasdaq: ABIO), a biopharmaceutical company developing genetically-targeted therapies for heart failure and other cardiovascular diseases, announced today that data from the pivotal Phase 3 BEST trial of Gencaro™ (bucindolol hydrochloride) in patients with advanced chronic heart failure (CHF) was presented at the American College of Cardiology 58th Annual Scientific Session being held March 29-31, 2009 in Orlando, Florida. The trial results demonstrated that, in a demographically-diverse group of primarily U.S. patients with New York Heart Association (NYHA) class III and IV heart failure, Gencaro treatment resulted in a near significant overall survival benefit and statistically significant benefits in slowing progression of heart failure. These results were observed despite the premature termination of the trial, with only 92 percent of the projected primary endpoint events available and average follow-up shortened by 12 months.

Analyzed in accordance with the U.S. Food and Drug Administration (FDA)-reviewed, pre-specified statistical analysis plan, the primary endpoint of mortality was reduced in all BEST trial patients on Gencaro by 13 percent (hazard ratio (HR) 0.87; p=0.053). All eight secondary endpoints of the trial were positive and statistically significant. As pre-specified with the FDA, the composite endpoint of heart failure progression was the most important secondary endpoint, with Gencaro shown to be superior to placebo for slowing progression of heart failure (HR 0.80, p=0.00003), and for the endpoint's components of heart failure-related mortality (HR 0.85, p=0.042), heart failure-related hospital admission (HR 0.77, p=0.00002), and heart failure-related emergency room visits (HR 0.74, p=0.024).

“The results of the BEST trial, analyzed according to the pre-specified regulatory statistical analysis plan, are the foundation of our New Drug Application currently under review by the FDA with a PDUFA date of May 31, 2009,” commented Dr. Michael R. Bristow, ARCA’s founder and chief science and medical officer. “We believe there is a substantial need for new heart failure therapies for which response can be better predicted pharmacogenetically prior to the onset of therapy, and that Gencaro may

help to address these needs.”

About BEST

The Beta Blocker Evaluation of Survival Trial (BEST) was a randomized, placebo-controlled trial in patients with moderate to severe heart failure (NYHA Class III or IV), testing the hypothesis that beta-blockers reduce mortality and morbidities in patients with heart failure. BEST was jointly funded by the Veteran’s Administration Cooperative Clinical Studies Program (VA CCSP) and the National Heart, Lung and Blood Institute (NHLBI). As a result of the quality of data from existing studies in patients with heart failure and its tolerability, Gencaro was chosen as the beta-blocker for evaluation in this trial.

In this double-blind trial, conducted between 1995 and 1999, a total of 2,708 patients with heart failure designated as NYHA functional class III (92 percent) or IV (8 percent) and a left ventricular ejection fraction \leq 35 percent were randomly assigned to treatment with either Gencaro (1,354 patients) or placebo (1,354 patients) and followed for the primary endpoint of death from any cause (all-cause mortality), and the highest ranking secondary endpoint of heart failure progression (composed of heart failure-related mortality or cardiac transplantation or heart failure-related hospitalization or heart failure-related emergency room visit). Additional secondary endpoints included: cardiovascular mortality (HR 0.84); mortality or cardiac transplantation (HR 0.86); heart failure hospitalization (HR 0.77); myocardial infarction (HR 0.53); change in need for co-therapy; quality of life (QOL); left ventricular ejection fraction (LVEF). Efficacy analyses were based on Intention to Treat (ITT).

Preliminary results from the BEST trial were reported in 2001, following early termination of the study due to loss of investigator equipoise. Pharmacogenetic results of a large (n=1040) DNA substudy indicating enhancement of therapeutic index by the use of adrenergic receptor polymorphisms have been extensively reported. However, the overall trial results analyzed according to the FDA-negotiated pre-specified statistical analysis plan (SAP) have never been reported.

The poster presented at the ACC conference is available on ARCA’s website at www.arcabiopharma.com.

About ARCA biopharma

ARCA biopharma, Inc. is dedicated to developing and commercializing genetically targeted therapies for heart failure and other cardiovascular disease. The Company’s lead product candidate, Gencaro™ (bucindolol hydrochloride), 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 it believes predict individual patient response to Gencaro, giving it the potential to be the first genetically-targeted heart failure treatment. The New Drug Application for approval of Gencaro for the indication of chronic heart failure, including the proposed brand name, is currently under review by the U.S. Food and Drug Administration with a Prescription Drug User Fee Act (PDUFA) date of May 31, 2009. ARCA is collaborating with Laboratory Corporation of America to develop the companion genetic test for Gencaro. The Company’s second compound in development, NU172, is a direct thrombin inhibitor which has completed Phase 1b development for use as a potential

short-acting anticoagulant during medical or surgical procedures. For more information please visit www.arcabiopharma.com.

Safe Harbor Statement

This press release contains "forward-looking statements" which include, without limitation, statements regarding the potential benefits of Gencaro treatment in patients with heart failure, including overall survival benefit and benefit in slowing progression of heart failure; that there is a substantial need for new heart failure therapies and that Gencaro may help to address these needs; the potential for Gencaro to be the first genetically targeted treatment for heart failure; and the clinical, regulatory and commercial potential of ARCA's development compounds, Gencaro and NU172, which statements are hereby identified as "forward-looking statements" for purposes of the safe harbor provided by the Private Securities Litigation Reform Act of 1995. Such statements are based on management's current expectations and involve risks and uncertainties. Actual results and performance could differ materially from those projected in the forward-looking statements as a result of many factors, including, without limitation, the risk that ARCA does not successfully integrate the business operations of the parties to its recent business combination; the company's inability to further identify, develop and achieve commercial success for products and technologies; the risk that the company's financial resources will be insufficient to meet the company's business objectives; uncertainties relating to drug discovery and the regulatory approval process; clinical development processes; enrollment rates for patients in the company's clinical trials; changes in relationships with strategic partners and dependence upon strategic partners for the performance of critical activities under collaborative agreements; and, the impact of competitive products and technological changes. These and other factors are identified and described in more detail in ARCA's filings with the SEC, including without limitation ARCA's annual report on Form 10-K for the year ended December 31, 2008 and subsequent filings. We disclaim any intent or obligation to update these forward-looking statements.

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