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**ARCA BIOPHARMA ANNOUNCES PLANNED EXPANSION OF GENCARO  
DEVELOPMENT TO ATRIAL FIBRILLATION**

**Phase 3 Trial of Gencaro in Heart Failure Patients with Atrial Fibrillation Planned To Begin  
Enrollment in 1H 2012**

**Gencaro Potentially First Genetically-Targeted Treatment for Prevention of Atrial  
Fibrillation**

*Broomfield, CO, May 26, 2011* – ARCA biopharma, Inc. (Nasdaq: ABIO), a biopharmaceutical company developing genetically-targeted therapies for cardiovascular diseases, today announced that it is planning to expand the development of Gencaro, its lead cardiovascular drug candidate, to atrial fibrillation, a disease that affects more than 2.4 million patients in the United States. Subject to obtaining additional funding, the Company anticipates initiating patient enrollment of a Phase 3 clinical trial in the first half of 2012 to evaluate Gencaro in patients who have symptomatic atrial fibrillation and heart failure with reduced left ventricular ejection fraction (HFREF).

“At ARCA, we believe a personalized medicine approach to drug development, tailoring medical treatment to the individual genetic characteristics of each patient, can enable more effective therapies, improve patient outcomes and reduce healthcare costs,” said Dr. Michael R. Bristow, President and Chief Executive Officer of ARCA. “If our development program for Gencaro in atrial fibrillation successfully confirms atrial fibrillation data from the prior BEST study, Gencaro has the potential to be the first genetically targeted treatment for the prevention of this important cardiovascular disorder.”

**Atrial Fibrillation**

Atrial fibrillation is a disorder in which the normally regular and coordinated contraction pattern of the heart's two small upper chambers (the atria) becomes irregular and uncoordinated. The irregular contraction pattern associated with atrial fibrillation causes blood to pool in the atria, predisposing the formation of clots. These clots may travel from the heart and become lodged in the arteries leading to the brain and other organs, thereby blocking necessary blood flow and potentially resulting in stroke. In addition, in patients with HFREF, new onset atrial fibrillation may also contribute to worsening heart failure and increased risk of death.

Studies estimate atrial fibrillation affected between 2.4 and 3 million Americans in 2005. Those same studies estimate the prevalence of atrial fibrillation will likely increase to between 3.8 million and 4.8 million by 2025. Industry estimates expect the atrial fibrillation drug market in developed countries to increase more than eight-fold, from \$843 million in 2009 to \$6.8 billion in 2019. The Company believes there is an unmet medical need for new atrial fibrillation treatments that have fewer side effects than currently available therapies and are more effective, particularly in patients with HFREF, where most of the approved atrial fibrillation drugs are contra-indicated or have warnings in their prescribing information.

### **Gencaro Data in Atrial Fibrillation**

Clinical data from BEST, a Phase 3 trial in 2,708 patients with advanced heart failure, indicate that Gencaro may have a potentially enhanced and pharmacogenetically-influenced effect in reducing and preventing atrial fibrillation. In that trial, patients in the Gencaro arm demonstrated a reduction in the risk of new onset atrial fibrillation time to event compared to patients in the placebo arm of 41% (atrial fibrillation measured as an adverse event/serious adverse event or as detected on surveillance ECGs, time to event analysis,  $p = 0.0004$ ). In a 1,040 patient DNA substudy of BEST, Gencaro exhibited pharmacogenetic enhancement and differentiation for atrial fibrillation prevention in patients with a specific genotype (beta<sub>1</sub>389 arginine homozygous (Arg/Arg) adrenergic receptor (AR); approximately 47% of the patients). These patients experienced a 74% ( $p = 0.0003$ ) reduction in risk of atrial fibrillation versus no detectable reduction in patients who had alternative genotypes (beta<sub>1</sub>389 Gly carriers; 53% of the patients). The Company believes this data supports the potential ability of Gencaro to prevent atrial fibrillation in patients who have the genotype the Company believes responds most favorably to Gencaro.

In prior placebo controlled trials in chronic HFREF, most studies comparing beta-blockers to placebo have detected a positive signal for prevention of atrial fibrillation, with an event rate reduction averaging approximately 27%, even though atrial fibrillation had not been a pre-specified primary or secondary endpoint in these studies. Currently, no beta-blocker has been approved by the U.S. Food and Drug Administration for the prevention of atrial fibrillation in heart failure patients.

### **Gencaro Phase 3 Atrial Fibrillation Clinical Trial**

The Company plans to conduct a Phase 3, multi-center, randomized, double-blind clinical trial of Gencaro in approximately 300-400 new onset atrial fibrillation patients with HFREF. The Company believes the planned study will provide important clinical data on the safety and efficacy of Gencaro in this patient population and additional information on the pharmacogenetic selectivity of Gencaro. The primary endpoint of the trial will be time to recurrent symptomatic atrial fibrillation after electrical cardioversion. The atrial fibrillation development program was recently presented by Dr. Bristow at the Heart Failure Congress 2011, organized by the Heart Failure Association of the European Society of Cardiology.

The Company is planning for the atrial fibrillation trial to compare Gencaro to the beta-blocker

metoprolol CR/XL in patients with the genotype (homozygous arginine position of the beta<sub>1</sub>389 adrenergic receptor) in which Gencaro appears to demonstrate therapeutic enhancement. Metroprolol CR/XL does not appear to have enhancement of efficacy in patients with this genotype. The Company believes the planned trial would take approximately two years from enrollment of the first patient to completion. Subject to obtaining additional financing, the Company anticipates initiating patient enrollment in the trial in the first half of 2012.

### **About ARCA biopharma**

ARCA biopharma is dedicated to developing genetically-targeted therapies for cardiovascular diseases. The Company's lead product candidate, Gencaro™ (bucindolol hydrochloride), is an investigational, pharmacologically unique beta-blocker and mild vasodilator being developed for the treatment of chronic heart failure and the prevention of atrial fibrillation in patients with heart failure. ARCA has identified common genetic variations in the cardiovascular system that it believes interact with Gencaro's pharmacology and may predict individual patient response to Gencaro, giving it the potential to be the first genetically-targeted heart failure and/or atrial fibrillation prevention treatment. ARCA is collaborating with Laboratory Corporation of America to develop the companion genetic test for Gencaro. For more information please visit [www.arcabiopharma.com](http://www.arcabiopharma.com).

### **Safe Harbor Statement**

This press release contains "forward-looking statements" for purposes of the safe harbor provided by the Private Securities Litigation Reform Act of 1995. These statements include, but are not limited to, statements regarding the ability of genetic variations to predict individual patient response to Gencaro; the potential for Gencaro to be the first genetically-targeted heart failure and/or atrial fibrillation prevention treatment; the projected increase in prevalence of atrial fibrillation; the projected increase in the size of the atrial fibrillation drug market in developed countries; and, the potential for the planned atrial fibrillation clinical trial provide important data on the safety and efficacy of Gencaro in the trial population. 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 risks and uncertainties associated with: the Company's financial resources and whether they will be sufficient to meet the Company's business objectives and operational requirements; the protection and market exclusivity provided by the Company's intellectual property; risks related to the drug discovery and the regulatory approval process; 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 the Company's annual report on Form 10-K for the year ended December 31, 2010 and subsequent filings. The Company disclaims any intent or obligation to update these forward-looking statements.

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