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**ARCA RECEIVES FDA FAST TRACK DESIGNATION FOR GENCARO™
DEVELOPMENT IN GENOTYPE-DEFINED HEART FAILURE POPULATION**

Broomfield, CO, November 23, 2009 – ARCA biopharma, Inc. (Nasdaq: ABIO) today announced that the U.S. Food and Drug Administration (FDA) has designated as a Fast Track development program the investigation of Gencaro™, the Company's investigational, pharmacologically unique beta-blocker and mild vasodilator, for the reduction of cardiovascular mortality and cardiovascular hospitalizations in a genotype-defined heart failure population. The Company intends to submit a study protocol for review under the FDA's Special Protocol Assessment (SPA) process for the design of a clinical trial to assess the safety and efficacy of Gencaro in approximately 3,000 patients with chronic heart failure who have the genotype that appears to respond most favorably to Gencaro.

According to the FDA's Fast Track Guidance document, Fast Track programs are designed to facilitate the development and expedite the review of new drugs that are intended to treat serious or life-threatening conditions and that demonstrate the potential to address unmet medical needs.

“Fast Track designation for the Gencaro development program is an important acknowledgement of the need for advancements in the treatment of patients with chronic heart failure, a disease afflicting approximately 6 million people in the United States with approximately 550,000 new cases diagnosed each year,” said Michael R. Bristow, President and Chief Executive Officer of ARCA. “If the SPA is approved by the FDA and the Company is able to obtain financing, this proposed clinical trial would be the first full sized cardiovascular trial performed in a genetically defined subpopulation to predict efficacy enhancement by the tested drug. As such, the proposed trial would be a landmark undertaking in pharmacogenetic drug development.”

ARCA anticipates that the proposed trial protocol will be a superiority comparison to the beta-blocker metoprolol CR/XL, which is approved for heart failure and other indications. The Company believes that the proposed trial protocol will involve an interim data analysis at a pre-specified number of primary endpoints, which could serve as the clinical effectiveness basis for FDA approval if the results meet certain predefined criteria. If agreed to by the FDA, the Company anticipates that the proposed trial could reach the specified number of endpoint events as soon as approximately two years after the trial begins. The Company expects that the SPA submission will propose that a composite of cardiovascular mortality and cardiovascular hospitalization serve as the primary endpoint of the trial. Any proposed trial protocol must be

reviewed and agreed on by the FDA and the final trial protocol may be significantly different from the Company's initial SPA submission.

The Company anticipates that it will submit the study protocol for review under the SPA process in the fourth quarter of 2009. Subject to the timing and outcome of the FDA's review of the SPA submission, and subject to the Company's ability to obtain sufficient funding, the Company currently expects it could begin the proposed trial in late 2010 or the first half of 2011.

Fast Track drug development designation is included in the FDA Modernization Act of 1997 (FDAMA) as a formal process to enhance interactions with the FDA during drug development. A drug development program with Fast Track designation would be eligible for consideration for some or all of the following programs for expediting development and review: scheduled meetings to seek FDA input into development plans, priority review of the New Drug Application (NDA), the option of submitting portions of an NDA prior to submission of the complete application and potential accelerated approval.

About Gencaro™

Gencaro™ (bucindolol hydrochloride) is a pharmacologically unique beta-blocker and mild vasodilator being developed for the treatment of chronic heart failure (HF). Gencaro is an oral tablet formulation, dosed twice daily. Gencaro is considered part of the beta-blocker class because of its property of blocking beta-1 as well as beta-2 receptors in the heart, preventing these receptors from binding with other molecules that would otherwise activate the receptor. Because of its mild vasodilator effects, the Company believes Gencaro is well-tolerated in patients with advanced HF.

The active pharmaceutical ingredient in Gencaro, bucindolol hydrochloride, has been tested clinically in approximately 3,000 patients. Gencaro was the subject of a Phase 3 heart failure mortality trial of over 2,700 patients, mostly in the U.S., known as the "BEST" trial. The BEST trial included a DNA bank of over 1,000 patients, which was used to evaluate the effect of genetic variation on patients' response to Gencaro. In this study, Gencaro appeared to produce enhanced clinical outcomes in the 47% of patients who were homozygous for the amino acid position 389 arginine polymorphism of the beta-1 adrenergic receptor, a variant with higher functional activity and higher affinity for norepinephrine, which the Company believes is the most favorable genotype for a positive response to Gencaro. Gencaro is the only beta blocker that has been shown to lead to inactivation of human myocardial constitutively active beta-1 receptors, which the Company believes is important because this potentially adverse signaling state is more prevalent in the Arg 389 beta-1 receptor variant.

In addition, ARCA and its scientific collaborators have recently identified and published evidence that an additional genetic variant, a deletion/insertion polymorphism of the alpha-2C adrenergic receptor may also influence patient responses to Gencaro. Subject to approval by the FDA, ARCA's collaborator, Laboratory Corporation of America anticipates introducing a test for these genetic markers concurrent with the potential market launch of Gencaro, potentially making Gencaro the first genetically-personalized cardiovascular drug.

About Heart Failure

Heart failure, or HF, is a chronic, progressive condition in which a problem with the structure or

function of the heart impairs its ability to supply sufficient blood flow to meet the body's needs for blood and oxygen. Common causes of heart failure include myocardial infarction and other forms of ischemic heart disease, hypertension, valvular heart disease and cardiomyopathy. Heart failure is one of the largest health care problems in the United States and the rest of the world. Industry sources estimate that about 6 million Americans have HF and nearly 550,000 new patients are diagnosed annually. In addition, HF is the underlying reason for approximately 12 to 15 million annual visits to physicians, 6.5 million annual hospital days and over \$34 billion in direct and indirect annual healthcare costs.

Beta-blockers are part of the current standard of care for HF, and are considered to be among the most effective drug classes for the disease. However, a significant percentage of eligible patients in the United States is not being treated with, or does not tolerate or respond well to, the beta-blockers currently approved for the treatment of HF. ARCA believes that new therapies for which patient response can be predicted before a drug is prescribed can help improve the current standard of practice in the treatment of HF.

About Pharmacogenomics

Pharmacogenomics is the study of genetic polymorphisms that underlie individual differences in responses to therapeutic drugs. Pharmacogenomics includes identifying candidate genes and polymorphisms, correlating these polymorphisms with possible therapies, predicting drug response and clinical outcomes, reducing adverse events and selection, and selecting dosing of therapeutic drugs on the basis of genotype. One goal of pharmacogenomics is to customize drugs for defined sub-populations of patients.

A DNA sub-study of patients from the BEST Phase 3 heart failure mortality trial of bucindolol, the active pharmaceutical ingredient in Gencaro, indicated that the combinations of beta-1 389 and alpha-2C polymorphisms in individual patients in the trial appeared to influence the response to bucindolol. As a result, ARCA believes heart failure patients may be categorized into three groups for potential patient response to Gencaro:

- The group with the genotype the Company believes is most favorable to Gencaro, constituting an estimated 47%-50% of the US population. These patients are homozygous arginine at the amino acid position 389 beta-1 adrenergic receptor polymorphism.
- A second "favorable" group, constituting an estimated 40% of the US population, which may benefit therapeutically from Gencaro, although potentially not as much of a benefit as the most favorable group.
- A third "unfavorable" group, constituting an estimated 10%-13% of the US population, which the Company believes should not receive Gencaro.

About ARCA biopharma

ARCA biopharma is dedicated to developing 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. 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. ARCA is collaborating with Laboratory Corporation of America to develop the companion genetic test for Gencaro. For more information please visit 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 significance of Fast Track designation; the timing and outcome of the Company's proposed SPA submission, regulatory review and potential approval of the Company's New Drug Application for Gencaro; the prospects for ARCA's providing sufficient information in a timely manner as requested in the FDA's Complete Response Letter; and, the Company's ability to fund future operations. 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 Company's ability to complete a strategic transaction to support the continued development Gencaro, and/or obtain additional financing; the Company's ability to identify, develop and achieve commercial success for products and technologies; 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, 2008, the Company's quarterly report on Form 10-Q for the quarter ended September 30, 2009 and subsequent filings. The Company disclaims any intent or obligation to update these forward-looking statements.

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