



Contact:

Derek Cole

Vice President, Investor Relations & Corporate Communications

720.940.2163

derek.cole@arcabiopharma.com

ARCA ANNOUNCES SUBMISSION OF A REQUEST FOR SPECIAL PROTOCOL ASSESSMENT FOR GENCARO™ DEVELOPMENT IN GENOTYPE-DEFINED HEART FAILURE POPULATION

Broomfield, CO, December 22, 2009 – ARCA biopharma, Inc. (Nasdaq: ABIO) today announced that it has submitted a study protocol for review under the U.S Food and Drug Administration’s (FDA) 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. Gencaro is the Company’s investigational, pharmacologically unique beta-blocker and mild vasodilator. The FDA has previously designated the investigation of Gencaro for the reduction of cardiovascular mortality and cardiovascular hospitalizations in a genotype-defined heart failure population as a fast track development program. An SPA is an agreement with the FDA that the proposed trial protocol design, clinical endpoints and statistical analyses are acceptable to support regulatory approval. For further information, please visit the FDA website, www.fda.gov.

“Submission of our trial protocol for review under the FDA’s SPA process is an important milestone for ARCA and Gencaro,” said Michael R. Bristow, President and Chief Executive Officer of ARCA. “We believe that Gencaro has the potential to provide a needed advancement 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.”

The proposed trial protocol includes a superiority comparison to the beta-blocker metoprolol CR/XL, which is approved for heart failure and other indications. The proposed trial protocol also includes an interim data analysis at a pre-specified number of primary endpoints, the results of which could allow ARCA to formally submit a complete response to the FDA’s Complete Response Letter and could serve as the clinical effectiveness basis for FDA approval if the results meet certain predefined criteria agreed upon with the FDA during the SPA process. If the proposed protocol and criteria are 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 SPA submission proposes 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.

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.

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.

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 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 timing and outcome of the Company's SPA submission; the significance of Fast Track designation; 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.

###