



**ARCA BIOPHARMA ANNOUNCES 150TH PATIENT RANDOMIZED INTO THE
GENETIC-AF PHASE 2B/3 CLINICAL TRIAL**

Outcome of DSMB Interim Efficacy Analysis Anticipated in the Third Quarter of 2017

**GENETIC-AF Evaluating Gencaro as Potentially First Genetically-Targeted
Treatment for Atrial Fibrillation**

Westminster, CO, January 18, 2017 – ARCA biopharma, Inc. (Nasdaq: ABIO), a biopharmaceutical company applying a precision medicine approach to developing genetically-targeted therapies for cardiovascular diseases, today announced that the 150th patient has been randomized into GENETIC-AF, a seamless Phase 2B/3 clinical trial evaluating GencaroTM (bucindolol hydrochloride) as a potential treatment for atrial fibrillation (AF).

The GENETIC-AF Data Safety Monitoring Board (DSMB) will conduct a Phase 2B interim efficacy, safety and futility analysis of evaluable data from at least 150 patients. The Company expects the outcome of this interim analysis in the third quarter of 2017.

“This is an important milestone for the Gencaro atrial fibrillation development program and a terrific accomplishment for the team here at ARCA,” commented Dr. Michael Bristow, ARCA’s President and CEO. “We are grateful for the continuing support of the physicians, clinical investigators and patients participating in the GENETIC-AF trial evaluating GencaroTM as potentially the first genetically-targeted treatment for atrial fibrillation. The Gencaro development program, if successful in GENETIC-AF, may also herald a new era of pharmacogenetically developed cardiovascular drugs.”

Phase 2B Interim Efficacy Analysis

GENETIC-AF is a seamless Phase 2B/3 adaptive design superiority trial evaluating the effectiveness of Gencaro for the prevention of recurrent atrial fibrillation or flutter (AF/AFL) in heart failure patients with reduced left ventricular ejection fraction (HFrEF). The DSMB will perform a pre-specified interim analysis of unblinded efficacy data when at least 150 patients have evaluable data. A randomized patient has evaluable data either when they experience their first composite endpoint event, AF/AFL or all-cause mortality, or after completion of the 24-week primary endpoint follow-up period. The analysis will be conducted for detection of evidence of safety and superior efficacy of Gencaro versus the active comparator, metoprolol succinate (TOPROL-XL).

The prospectively defined features of this analysis include: 1) an estimate of Gencaro effectiveness relative to TOPROL-XL; and, 2) an assessment of safety as characterized by adverse events. The

relative benefit estimate will utilize Bayesian statistical methods to calculate the predictive probability of the Phase 3 patient cohort hazard ratio based on the interim Phase 2B data. Prospectively defined ranges of predictive probabilities have been predetermined to define three potential outcomes based on the projection of the Phase 2B interim results:

- 1) transition the trial to Phase 3 based on a likelihood of achieving a statistically significant hazard ratio in favor of Gencaro (evidence of an effectiveness signal consistent with pretrial assumptions) and enroll up to a total of 620 patients (including the Phase 2B patients);
- 2) completion of the Phase 2B stage of the trial including 24-week follow-up of all randomized subjects (approximately 250 patients), based on an intermediate result that is potentially favorable but does not support transition of the trial to Phase 3 or;
- 3) immediate termination of the trial due to futility.

The Company, in collaboration with the trial Steering Committee, will determine the best path forward for the trial based on the DSMB recommendation from this interim analysis. The unblinded statistical data available to the DSMB will not be disclosed to the Company or the public. The Company projects that the outcome of the DSMB interim analysis and recommendation will be available in the third quarter of 2017.

GENETIC-AF Clinical Trial

GENETIC-AF is a seamless Phase 2B/3, adaptive design, multi-center, randomized, double-blind, superiority clinical trial comparing the safety and efficacy of Gencaro to Toprol-XL (metoprolol succinate) for the prevention of recurrent AF/AFL in HFrEF patients. Eligible patients will have HFrEF, a history of paroxysmal AF (episodes lasting 7 days or less) or persistent AF (episodes lasting more than 7 days and less than 1 year) in the past 6 months, and the beta-1 389 arginine homozygous genotype that the Company believes responds most favorably to Gencaro. The primary endpoint of the study is time to first event of symptomatic AF/AFL or all-cause mortality. The trial is currently enrolling patients in the United States, Canada and Europe.

About ARCA biopharma

ARCA biopharma is dedicated to developing genetically-targeted therapies for cardiovascular diseases through a precision medicine approach to drug development. The Company's lead product candidate, Gencaro™ (bucindolol hydrochloride), is an investigational, pharmacologically unique beta-blocker and mild vasodilator being developed for atrial fibrillation. 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 atrial fibrillation prevention treatment. ARCA has a collaboration with Medtronic, Inc. for support of the GENETIC-AF trial. For more information, please visit www.arcabio.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 potential that the data from 150 patients will support a

recommendation that the GENETIC-AF trial transition to Phase 3, the potential timeline for GENETIC-AF trial activities and related recommendations of the DSMB, potential timing for patient enrollment in the GENETIC-AF trial, the sufficiency of the Company's capital to support its operations, the potential for genetic variations to predict individual patient response to Gencaro, Gencaro's potential to treat atrial fibrillation, future treatment options for patients with atrial fibrillation, and the potential for Gencaro to be the first genetically-targeted atrial fibrillation prevention treatment. 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; results of earlier clinical trials may not be confirmed in future trials, 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 Securities and Exchange Commission, including without limitation the Company's annual report on Form 10-K for the year ended December 31, 2015, and subsequent filings. The Company disclaims any intent or obligation to update these forward-looking statements.

Investor & Media Contact:

Derek Cole

720.940.2163

derek.cole@arcabio.com

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