



**ARCA BIOPHARMA ANNOUNCES DATABASE LOCK FOR GENETIC-AF
PHASE 2B INTERIM EFFICACY ANALYSIS – DSMB RECOMMENDATION
ANTICIPATED IN AUGUST 2017**

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

Gencaro Development Program Previously Granted Fast Track Designation by U.S. FDA

Westminster, CO, June 20, 2017 – ARCA biopharma, Inc. (Nasdaq: ABIO), a biopharmaceutical company applying a precision medicine approach to developing genetically-targeted therapies for cardiovascular diseases, today announced database lock for the GENETIC-AF Phase 2B interim efficacy analysis, to be conducted by the trial Data Safety Monitoring Board (DSMB). GENETIC-AF is a seamless design Phase 2B/3 clinical trial evaluating Gencaro™ (bucindolol hydrochloride) as a potential treatment for atrial fibrillation (AF). The Company expects to announce the DSMB’s recommendation based on this interim analysis in August 2017. The Gencaro development program has previously been granted Fast Track designation by the U.S. Food and Drug Administration (FDA).

“Reaching database lock for the interim analysis and the collection and processing of trial data for the DSMB mark important points in the development of Gencaro. We are hopeful a positive DSMB recommendation will further support our data-driven rationale for development of the first genetically-targeted treatment candidate for atrial fibrillation in heart failure patients,” commented Dr. Michael Bristow, ARCA’s President and CEO. “Based on our view of the strength of prior AF prevention data from the BEST trial and pursuant to discussions with the FDA, we have incorporated a seamless design feature for this trial. Beyond the potential for a positive recommendation of completing GENETIC-AF as a Phase 2B trial, the interim analysis allows for a recommendation to advance directly to Phase 3 if the analyzed Phase 2B cohort is responding favorably to treatment, with retention of these patients’ data in the final Phase 3 analysis. This approach substantially reduces the number of patients required to complete Phase 3, potentially allowing for a more rapid development program devoid of the risks of starting a new trial dissociated from a positive Phase 2 experience.”

GENETIC-AF Clinical Trial

GENETIC-AF is an adaptive, seamless design Phase 2B/3, multi-center, randomized, double-blind, superiority clinical trial comparing the safety and efficacy of Gencaro to Toprol-XL (metoprolol succinate) for the treatment and prevention of recurrent atrial fibrillation or flutter (AF/AFL) in heart failure patients with reduced left ventricular ejection fraction (HFrEF). 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 ARCA 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 GENETIC-AF trial design has been reviewed by the FDA. The trial is currently enrolling patients in the United States, Canada and Europe.

Phase 2B Interim Efficacy Analysis

The DSMB will perform a pre-specified interim analysis of unblinded efficacy data from a minimum of 150 patients with 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 primary analysis will include data from all randomized subjects at the time of database lock.

The primary analysis will be conducted to evaluate the evidence for safety and superior efficacy of Gencaro versus the active comparator, metoprolol succinate (TOPROL-XL).

The prospectively defined features of this analysis include an estimate of Gencaro effectiveness relative to TOPROL-XL and an assessment of safety as characterized by adverse events. The primary analysis method will generate predictive probability of success (PPoS) values that will be compared to prespecified PPoS boundaries constructed from Bayesian statistical modeling. Prospectively defined PPoS ranges 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, if the PPoS results fall below the boundary for completion as a Phase 2 trial.

ARCA, in collaboration with the trial Steering Committee, will determine the most appropriate 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.

About ARCA biopharma

ARCA biopharma is dedicated to developing genetically-targeted therapies for cardiovascular diseases through a precision medicine approach to drug development. ARCA's lead product candidate, GencaroTM (bucindolol hydrochloride), is an investigational, pharmacologically unique beta-blocker and mild vasodilator being developed for the potential treatment of patients with atrial fibrillation and HFrEF. 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. The Gencaro development program has been granted Fast Track designation by the U.S. Food and Drug Administration (FDA). 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 at least 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 ARCA's capital to support its operations, the potential for genetic variations to predict individual patient response to Gencaro, Gencaro's potential to treat AF, future treatment options for patients with AF, and the potential for Gencaro to be the first genetically-targeted AF 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: ARCA's financial resources and whether they will be sufficient to meet its business objectives and operational requirements; results of earlier clinical trials may not be confirmed in future trials; the protection and market exclusivity provided by ARCA'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 ARCA's annual report on Form 10-K for the year ended December 31, 2016, and subsequent filings. ARCA disclaims any intent or obligation to update these forward-looking statements.

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