ARCA BIOPHARMA ANNOUNCES GENETIC-AF DATA AND SAFETY MONITORING BOARD RECOMMENDATION TO COMPLETE PHASE 2B GENETIC-AF CLINICAL TRIAL BASED ON EFFICACY AND SAFETY DATA IN PHASE 2B INTERIM ANALYSIS

ARCA Estimates Reporting Top-line Phase 2B Data in the First Quarter of 2018

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

Westminster, CO, August 9, 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 GENETIC-AF trial Data and Safety Monitoring Board (DSMB) completed its pre-specified Phase 2B interim analysis. Based on its efficacy and safety review, the DSMB recommended completion of the Phase 2B trial with no changes to the trial design. GENETIC-AF is a clinical trial evaluating Gencaro™ (bucindolol hydrochloride) as a potential treatment for atrial fibrillation (AF). The Gencaro development program has been granted Fast Track designation by the U.S. Food and Drug Administration (FDA).

"The DSMB stated that there were no safety concerns and that the efficacy results met the prespecified criteria for continuing the Phase 2B trial to completion. We are pleased with the execution of the study thus far with major pretrial assumptions reflected in the trial to date, including genotype frequency, AF/AFL event rate and patient screening rates. We believe the DSMB recommendation is encouraging, as the trial is testing for superior efficacy over the active comparator, Toprol-XL," commented Dr. Michael Bristow, ARCA's President and CEO. "We are now focused on completing the Phase 2B trial, which we estimate should include approximately 50% more events than were available at the interim analysis. We look forward to sharing the top-line trial results late in the first quarter of next year, and reviewing the findings with the FDA."

GENETIC-AF Clinical Trial

GENETIC-AF is a Phase 2B, adaptive design, 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 enrolling patients in the United States, Canada and Europe. The Company estimates reporting top-line Phase 2B data late in the first quarter of 2018. ARCA believes that its current cash, cash equivalents and marketable

securities will be sufficient to fund its operations, at its projected cost structure, into the second quarter of 2018.

Interim Efficacy Analysis

The DSMB performed a pre-specified interim analysis of unblinded efficacy data from all patients randomized as of June 19, 2017. The primary analysis on the data from these patients was conducted to evaluate the evidence of safety and superior efficacy of Gencaro versus the active comparator, metoprolol succinate (TOPROL-XL).

The prospectively defined features of this analysis included an estimate of Gencaro effectiveness relative to TOPROL-XL and an assessment of safety as characterized by adverse events. The primary analysis method generated predictive probability of success (PPoS) values that were compared to prespecified PPoS boundaries constructed from Bayesian statistical modeling. Prospectively defined PPoS ranges had been predetermined to define three potential outcomes based on the projection of the Phase 2B interim results:

1) transition the trial to Phase 3;
2) completion of the Phase 2B stage of the trial, based on an intermediate result that is potentially favorable but does not support immediate 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.

Based on the efficacy and safety data of the interim analysis, the DSMB recommended completing the Phase 2B trial with no changes to the trial design. In order to maintain the integrity of the on-going double-blind clinical trial, the unblinded statistical data available to the DSMB has not and will not be disclosed to ARCA, the trial leadership, or the investigators until the Phase 2B trial is complete. ARCA estimates reporting top-line data for the Phase 2B trial late in the first quarter of 2018.

About Gencaro

Gencaro (bucindolol hydrochloride) is an investigational, pharmacologically unique beta-blocker and mild vasodilator being developed for the treatment of AF. Gencaro is considered part of the beta-blocker class of compounds because of its property of blocking both beta-1 and beta-2, receptors in the heart. The blocking of these receptors prevents them from binding with other molecules, primarily the neurotransmitter norepinephrine, or NE, which activate these receptors. ARCA believes that Gencaro is well-tolerated in cardiovascular patients because of its mild vasodilator effects. Originally developed by Bristol-Myers Squibb the active pharmaceutical ingredient in Gencaro, bucindolol hydrochloride, has been tested clinically in approximately 4,500 patients, including over 3,000 patients in seven clinical trials in HFrEF patients. Gencaro was the subject of a Phase 3 HF mortality trial in 2,708 patients, mostly in the United States, or 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.

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, Gencaro™ (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, currently in a Phase 2B clinical trial. 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 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 outcome of the Phase 2B interim analysis is suggestive of a potentially positive outcome for the full Phase 2 trial, or sufficient to transition to a Phase 3 trial in the future, the potential timeline for GENETIC-AF trial activities, potential timing for the announcement of topline data for the Phase 2B portion of 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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