ARCA BIOPHARMA ANNOUNCES COMPLETION OF GENETIC-AF PHASE 2B CLINICAL TRIAL

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

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ARCA Estimates Reporting Top-line Phase 2B Data in March 2018

Westminster, CO, January 8, 2018 – ARCA biopharma, Inc. (Nasdaq: ABIO), a biopharmaceutical company applying a precision medicine approach to developing genetically-targeted therapies for cardiovascular diseases, today announced the completion of patient follow-up for GENETIC-AF, a Phase 2B, double-blind, superiority clinical trial evaluating Gencaro™ (bucindolol hydrochloride) as a potential genetically-targeted treatment for atrial fibrillation (AF). All patients completed their last study visits and were transitioned off study drug by the end of December 2017. ARCA expects to report top-line Phase 2B data in March 2018.

"Completion of patient treatment in GENETIC-AF represents a key clinical milestone for ARCA and we look forward to reporting top-line data for the trial, which we estimate should include approximately 50% more events than were available at the previously conducted interim analysis," commented Dr. Michael Bristow, ARCA's President and CEO. "I would like to thank our clinical investigators as well as the patients and their families for their participation. We will continue working diligently to advance Gencaro's pharmacogenetic clinical and regulatory development."

GENETIC-AF Clinical Trial

GENETIC-AF is a Phase 2B, 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 atrial flutter (AF/AFL) in heart failure patients with reduced left ventricular ejection fraction (HFrEF). Eligible patients 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 GENETIC-AF Data and Safety Monitoring Board (DSMB) conducted a pre-specified interim analysis in August 2017. Based on its efficacy and safety review, the DSMB recommended completion of the Phase 2B trial and indicated there were no safety concerns. The other protocol specified options for the interim analysis were accelerated development that would have transitioned the trial seamlessly to a larger Phase 3 trial of approximately 620 patients, or immediately stopping for futility.

The Phase 2B trial enrolled 267 patients from the United States, Canada and Europe. All patients have completed their last study visits and transitioned off study drug. ARCA is currently performing final monitoring visits and anticipates having evaluable data for approximately 250 patients in the final Phase 2B analysis. 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.

As the trial was statistically powered for the larger Phase 3 population, the final Phase 2B analysis will follow the same Bayesian methodology that was employed in the DSMB interim analysis, i.e., modeling the predictive probability of success (PPOS) of a future 620-patient Phase 3 study based on the time to first event of AF/AFL or all-cause mortality endpoint.

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 timeline for GENETIC-AF trial activities, potential timing for the announcement of topline data for the Phase 2B GENETIC-AF trial, the expected features and characteristics of Gencaro, including 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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