



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

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

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

Westminster, CO, August 16, 2017 – [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 enrollment 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). ARCA expects to report top-line Phase 2B data late in the first quarter of 2018.

Two-hundred sixty-seven patients were randomized into the trial, slightly exceeding the target enrollment of 250 patients. The trial enrolled patients from the United States, Canada and Europe.

“We believe reaching our target enrollment 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 recently 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 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 of all patients randomized as of June 19, 2017. Based on its efficacy and safety review, the DSMB recommended completion of the Phase 2B trial with no changes to the trial design and indicated that there were no safety concerns.

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 sufficiency of ARCA's capital to support its operations, 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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