



**ARCA BIOPHARMA ANNOUNCES STEERING COMMITTEE  
OF LEADING INTERNATIONAL CARDIOLOGY AND ELECTROPHYSIOLOGY  
EXPERTS FOR PRECISION-AF PHASE 3 CLINICAL TRIAL**

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**Steering Committee to Provide Scientific Oversight and Guidance for Pivotal Phase 3  
Trial Evaluating Gencaro as Potentially the First Genetically-Targeted Treatment for  
Atrial Fibrillation**

Westminster, CO, April 23, 2019 – [ARCA biopharma, Inc.](#) (Nasdaq: ABIO), a biopharmaceutical company applying a precision medicine approach to developing genetically-targeted therapies for cardiovascular diseases, today announced the initial members of the Steering Committee for [PRECISION-AF](#), the Company’s planned Phase 3 trial evaluating [Gencaro™](#) (bucindolol hydrochloride) as potentially the first genetically-targeted treatment for atrial fibrillation. The Steering Committee is comprised of experts in the field of cardiology and electrophysiology, particularly in clinical development. The Company anticipates additional cardiology thought leaders joining the Steering Committee.

[Stuart J. Connolly](#), MD, Professor Emeritus, [Division of Cardiology at McMaster University](#) in Hamilton, Ontario, and [William T. Abraham](#), MD, College of Medicine Distinguished Professor, [Division of Cardiovascular Medicine at The Ohio State University Wexner Medical Center](#), have been appointed co-Chairs of the Steering Committee.

“We are thrilled to have such a distinguished group of clinicians and researchers participate on the PRECISION-AF Steering Committee,” said [Dr. Michael R. Bristow](#), President and Chief Executive Officer of ARCA. “This committee consists of experts in the fields of cardiology and electrophysiology, giving our anticipated PRECISION-AF clinical trial the benefit of experienced leadership that is at the forefront of clinical research for the treatment of heart failure patients who have concomitant atrial fibrillation.”

“I’m pleased to participate in this very well designed and scientifically valid trial.” said Dr. Connolly. “Atrial fibrillation is a growing problem where current medical therapy does not provide adequate treatment, particularly in heart failure populations for which there are few therapeutic options. I look forward to working with the team at ARCA to advance this potential new treatment for heart failure patients living with atrial fibrillation.”

Dr. Abraham said, “I am pleased to be closely involved with the anticipated PRECISION-AF trial, which we believe has the potential to be the first Phase 3 cardiovascular trial to prospectively demonstrate superior efficacy based on patient genotype. PRECISION-AF has the potential to demonstrate efficacy in heart failure with mid-range ejection fraction – a population with high unmet medical need and few therapeutic options that has been excluded from previous heart failure

and atrial fibrillation trials.”

Additional Steering Committee members are:

- [Inder Anand, MD](#) – Professor of Medicine, [University of Minnesota Medical School](#) and [VA Medical Center Minneapolis](#);
- [A. John Camm, MD](#) – Professor of Clinical Cardiology at [St George’s University of London, London, United Kingdom](#);
- [Jeff S. Healey, MD](#) – [Population Health Research Institute, McMaster University](#);
- [Jonathan P. Piccini, MD](#) – Director, Cardiac Electrophysiology Clinical Trials Program, [Duke University Medical Center](#) and [Duke Clinical Research Institute](#);
- [Michiel Rienstra, MD, PhD](#) – [University Medical Center Groningen, The Netherlands](#);
- [Dirk J. van Veldhuisen, MD, PhD](#) – Chairman of Cardiology at the [University Medical Center Groningen, The Netherlands](#);
- [Michel White, MD](#) – Director of the [Heart Failure Research Group at the Montreal Heart Institute](#); and,
- [Stephen B. Wilton, MD](#) – [Libin Cardiovascular Institute of Alberta, University of Calgary](#).

The Steering Committee will provide scientific oversight of PRECISION-AF and communicate its recommendations regarding trial conduct to the trial’s Data Safety Monitoring Board.

### **PRECISION-AF Clinical Trial**

PRECISION-AF is designed as a single, adequate and well-controlled Phase 3 clinical trial that may be sufficient to support a New Drug Application (NDA) submission for an AF indication if the objectives of the trial are achieved consistent with the requirements of Special Protocol Assessment (SPA) agreement with the U.S. Food and Drug Administration (FDA). The trial is designed as a double-blind, active-controlled, multicenter, international study comparing Gencaro with Toprol-XL (metoprolol succinate) for the prevention of AF recurrence or all-cause mortality (ACM) in HFmrEF patients. HFmrEF is defined as HF with a left ventricular ejection fraction (LVEF)  $\geq 40\%$  and  $< 50\%$ , which constituted approximately half of the enrolled population in the previous Phase 2 GENETIC-AF trial. PRECISION-AF is designed to enroll approximately 400 patients who have: HFmrEF, a recent AF event, and the genotype which responds most favorably to Gencaro. The primary endpoint of the trial will be time to first event of atrial fibrillation/atrial flutter (AF/AFL) or ACM during the 26-week Follow-up Period. In the recently completed GENETIC-AF trial, Gencaro showed a 58% treatment benefit compared to Toprol-XL in reducing AF recurrence in the HFmrEF population targeted for Phase 3 (hazard ratio = 0.42; 95% CI: 0.21, 0.86;  $p = 0.017$ ). With 400 patients (200 per arm) the trial will have 90% power at a p-value of

0.01 to detect a 45% treatment benefit for Gencaro compared to Toprol-XL. Subject to securing additional financing, ARCA anticipates initiating PRECISION-AF in the fourth quarter of 2019.

## **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 atrial fibrillation in heart failure patients with mid-range ejection fraction. 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 AF prevention treatment. The Gencaro development program has been granted Fast Track designation by FDA. ARCA is also developing AB171, a thiol-substituted isosorbide mononitrate, as a potential genetically-targeted treatment for heart failure and peripheral arterial disease (PAD). For more information, please visit [www.arcabio.com](http://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 ability of ARCA's financial resources to support its operations through the end of the second quarter of 2019, potential future development plans for Gencaro, including statements regarding the anticipated PRECISION-AF trial, the expected features and characteristics of Gencaro or AB171, including the potential for genetic variations to predict individual patient response to Gencaro, Gencaro's potential to treat AF, AB171's potential to treat HF, 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; ARCA may not be able to raise sufficient capital on acceptable terms, or at all, to continue development of Gencaro or to otherwise continue operations in the future; 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, 2018, and subsequent filings. ARCA disclaims any intent or obligation to update these forward-looking statements.*

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