



**ARCA BIOPHARMA ANNOUNCES SUBMISSION OF PATENT APPLICATION TO  
U.S. PATENT AND TRADEMARK OFFICE COVERING TREATMENT OF ATRIAL  
FIBRILLATION IN PATIENTS WITH HEART FAILURE**

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**Similar Applications to Be Filed in Europe, Canada, Japan and China**

Westminster, CO, May 13, 2019 – [ARCA biopharma, Inc.](#) (Nasdaq: ABIO), a biopharmaceutical company applying a precision medicine approach to developing genetically-targeted therapies for cardiovascular diseases, today announced it recently filed a provisional patent application with the [United States Patent and Trademark Office](#) (USPTO) covering [Gencaro](#)'s (bucindolol hydrochloride) potential treatment effect in preventing atrial fibrillation (AF) in patients with heart failure (HF).

The patent application is based on recent novel findings from the GENETIC-AF Phase 2B study of Gencaro, described in “GENETIC-AF: Bucindolol for the Maintenance of Sinus Rhythm in a Genotype-Defined Heart Failure Population,” [published](#) in *JACC: Heart Failure*, a journal of the American College of Cardiology. The new discoveries from the GENETIC-AF study that are covered by the patent application include the key findings that patients who developed AF and HF contemporaneously, and those who did not have long-standing AF and HF, experience a stronger treatment effect from Gencaro. Another unexpected observation from the study that is covered by the patent application is the relationship between Gencaro's treatment effect for preventing AF recurrence and left ventricular ejection fraction (LVEF), with greater treatment effects correlating directly with increasing LVEF; and with the strongest treatment effects observed in study populations with the highest LVEF (LVEF  $\geq$  45%; n = 57; hazard ratio = 0.39; p < 0.05).

ARCA believes this clinical data may be explained by both Gencaro's unique mechanism of action in its drug class, as well as by factors related to the pharmacotherapy of AF intersecting with HF. This clinical data will be important in guiding the planned Phase 3 development of Gencaro for the treatment of AF in patients with HF, particularly in patients with LVEF  $\geq$  40%.

ARCA believes that the findings from GENETIC-AF in the application merit a patent. The Company believes drugs in the beta-blocker class have not been adequately studied in HF patients with LVEF  $\geq$  40%, which includes HF patients with mid-range ejection fraction (HFmrEF) and HF patients with preserved ejection fraction (HFpEF). HFmrEF and HFpEF represent more than half of all heart failure and there are currently no therapies shown to be effective for the treatment of AF in these patients.

ARCA expects to file the provisional application internationally and seek patent protection in the major pharmaceutical markets including the United States, European Union, Canada, Japan and China.

## 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. 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) or follow the Company on [LinkedIn](#).

## 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 likelihood that any patents will be allowed based on the patent application, the ability of ARCA's financial resources to support its operations through the end of the third quarter of 2019, potential future development plans for Gencaro, 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 or PAD, 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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