ARCA BIOPHARMA ANNOUNCES POSITIVE OUTCOME OF END-OF-PHASE 2 MEETING WITH FDA ON GENCARO DEVELOPMENT FOR ATRIAL FIBRILLATION

- **Single Phase 3 trial may be sufficient for approval of atrial fibrillation indication**
- **Phase 3 clinical trial Special Protocol Assessment submission anticipated 3Q2018**
- **Gencaro is in development as potentially the first genetically-targeted treatment for patients with atrial fibrillation**
- **Gencaro development program previously granted Fast Track Designation by FDA**

Westminster, CO, July 31, 2018 – ARCA biopharma, Inc. (Nasdaq: ABIO), a biopharmaceutical company applying a precision medicine approach to developing genetically-targeted therapies for cardiovascular diseases, today announced that it has received guidance from the U.S. Food and Drug Administration (FDA) following an End-of-Phase 2 meeting regarding the Phase 3 program for ARCA's pharmacologically unique beta-blocker Gencaro as a potential genetically-targeted treatment for atrial fibrillation (AF) patients with heart failure (HF).

Based on review of the Phase 2 GENETIC-AF trial results, as well as its alignment with previous Phase 3 pharmacogenetic substudy data, the FDA stated that data from a single pivotal Phase 3 clinical trial may be sufficient to support approval of Gencaro for the treatment of AF in patients with HF. The Company, in consultation with the FDA, has established key elements of the Phase 3 clinical trial needed to support a New Drug Application (NDA), details of which will be confirmed via the FDA Special Protocol Assessment (SPA) process.

The FDA previously granted the Gencaro atrial fibrillation development program Fast Track Designation. As the Gencaro program is developing potentially the first genetically-targeted cardiovascular therapy, the FDA has suggested the Company submit a SPA application, which the Company anticipates submitting in the third quarter of 2018.

ARCA anticipates initiating the Phase 3 clinical trial subject to securing additional financing through a strategic partnership and/or additional sales of the Company's securities.

The pivotal Phase 3 clinical trial will likely entail a single randomized, active-controlled trial with the primary endpoint based primarily on AF Burden (AFB). AFB is defined as the amount of time per day a patient experienced AF, as measured by an implanted monitoring device. In the recently completed GENETIC-AF Phase 2B clinical trial, Gencaro showed a trend for 25% benefit over Toprol-XL in reducing AF recurrence as measured by AFB in a subgroup of patients with implanted devices in which AFB was monitored. For U.S. patients in this substudy, a trend for 51% benefit was observed.

The Company believes that patients in GENETIC-AF who had AF secondary to an underlying HF

pathophysiology showed evidence of superior benefit when treated with Gencaro compared to Toprol-XL. In contrast, patients in GENETIC-AF who had long-standing AF prior to the development of asymptomatic/mild HF did not appear to show benefit when treated with Gencaro compared to Toprol-XL (approximately 23% of the Phase 2 population). Accordingly, in the proposed Phase 3 clinical trial, the Company plans to exclude this non-responsive subgroup and focus on patients who likely have AF driven by their underlying HF.

"We are encouraged by the outcome of our End-of-Phase 2 meeting regarding the development path forward for Gencaro and the FDA's response to the data from our completed Phase 2B GENETIC-AF study," commented Dr. Michael Bristow, ARCA's President and CEO. "FDA concurrence to proceed into Phase 3 is an important milestone for ARCA and for patients suffering from AF and HF, an indication for which there is a significant unmet medical need and currently no FDA approved therapeutics."

Updates and further details regarding the planned Phase 3 clinical trial, including anticipated timing of recruitment, participating centers and investigators will be provided later this year and posted on www.clinicaltrials.gov.

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 (AF) and chronic heart failure with reduced left ventricular ejection fraction (HFrEF) which recently completed 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 AF 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 FDA. ARCA also plans to develop AB171, a thiol-substituted isosorbide mononitrate, as a potential genetically-targeted treatment for peripheral arterial disease (PAD) and for heart failure (HF). 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 ability of ARCA's financial resources to support its operations or any future clinical trials, the submission or approval of any SPA application, potential future development plans for Gencaro, including any plans regarding a Phase 3 clinical trial related thereto, 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 peripheral arterial disease or 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, 2017, and subsequent filings. ARCA disclaims any intent or obligation to update these forward-looking statements.

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