ARCA BIOPHARMA ANNOUNCES COMPLETION OF FDA PRE-IND CONSULTATION UNDER CORONAVIRUS TREATMENT ACCELERATION PROGRAM FOR AB201 AS A POTENTIAL TREATMENT FOR SEVERE COVID-19

- ***ARCA anticipates filing an IND for AB201 for COVID-19 in September 2020 and initiating Phase 2B clinical testing as early as Q4 2020***

Westminster, CO, August 12, 2020 – ARCA biopharma, Inc. (Nasdaq: ABIO), a biopharmaceutical company applying a precision medicine approach to developing genetically targeted therapies for cardiovascular diseases, today announced it has completed a pre-Investigational New Drug (IND) consultation with the U.S. Food and Drug Administration (FDA) under the Coronavirus Treatment Acceleration Program (CTAP). The FDA provided feedback for ARCA's clinical development plans for evaluating AB201 as a potential treatment for patients with severe COVID-19. With this feedback, ARCA anticipates submitting its IND application in September 2020 in preparation for initiating a Phase 2B clinical trial as early as the fourth quarter of this year.

A pre-IND meeting provides an opportunity for an open communication between the sponsor and the FDA to discuss the IND development plan and to obtain the FDA's guidance for clinical trials for the sponsor's new drug candidate. The FDA has created CTAP as a special emergency program for possible coronavirus therapies which is designed to use every available method to move new treatments to patients as quickly as possible, while evaluating safety and effectiveness.

Dr. Michael Bristow, ARCA's President and Chief Executive Officer, commented, "Receiving the FDA's guidance is an important step in developing and executing our clinical development program for AB201. With what we believe to be a strong scientific rationale, safety data from prior human clinical trials in over 700 patients, and a well-defined regulatory pathway, we believe AB201 has potential as a therapeutic treatment for COVID-19. AB201's differentiated mechanism of action may also allow for use in combination with other COVID-19 therapeutics and provide a potential treatment for those patients who cannot take vaccines or for whom vaccines are not effective."

About AB201 (rNAPc2)

AB201 is a small recombinant protein being developed as a potential treatment for RNA virus-associated disease, initially focusing on COVID-19. AB201 is a potent, selective inhibitor of tissue factor (TF), which has been identified as playing a central role in the inflammatory response to viral infections and in the process of viral dissemination. AB201 has previously undergone Phase 1 and Phase 2 testing in more than 700 patients, including as an anti-thrombotic agent in the setting of acute myocardial infarction (MI), where it showed efficacy in inhibiting the TF pathway and was well tolerated at therapeutic doses. Recent research suggests that the disease syndrome caused by coronavirus may have much in common with other severe infections in which the infection

process causes inappropriate activation of the coagulation system, resulting in serious complications. Recent mechanistic discoveries, as well as prior data from studies in non-human primates (NHPs) given lethal doses of Ebola or Marburg filoviruses demonstrating morbidity and mortality reductions, decreases in inflammatory biomarkers and reduction in viral load, indicate that AB201 may have important antiviral and anti-inflammatory activity in addition to its anticoagulant effects. The Company believes that collectively these observations provide a strong rationale for investigating AB201 as a treatment for COVID-19 and other RNA virus associated diseases.

About ARCA biopharma

ARCA biopharma is dedicated to developing genetically targeted therapies for cardiovascular diseases through a precision medicine approach to drug development. ARCA is developing AB201 as a potential treatment for diseases caused by RNA viruses, initially focusing on COVID-19. ARCA is also developing Gencaro™ (bucindolol hydrochloride), an investigational, pharmacologically unique beta-blocker and mild vasodilator, as a potential treatment for 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 atrial fibrillation (AF) prevention treatment. The U.S. FDA has granted the Gencaro development program Fast Track designation and a Special Protocol Assessment (SPA) agreement. For more information, please visit 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 potential future development plans for AB201 and Gencaro, the expected features and characteristics of AB201 and Gencaro, including the potential for genetic variations to predict individual patient response to Gencaro, Gencaro's potential to treat atrial fibrillation, AB201's potential to treat COVID-19 or any other RNA virus associated disease, future treatment options for patients with COVID-19, 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 AB201 or 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, 2019, and subsequent filings. ARCA disclaims any intent or obligation to update these forward-looking statements.

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