ARCA biopharma Announces Submission of IND Application to U.S. FDA for AB201 as a Potential Treatment for COVID-19

Westminster, CO, September 21, 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 submitted an Investigational New Drug (IND) application with the U.S. Food and Drug Administration (FDA) under the Coronavirus Treatment Acceleration Program (CTAP) to evaluate AB201 for the treatment of patients hospitalized with COVID-19. Pending FDA feedback, ARCA anticipates initiating the Phase 2b portion of a sequential Phase 2b/3 clinical evaluation of AB201 as early as the fourth quarter of this year.

Dr. Michael Bristow, ARCA's President and Chief Executive Officer, commented, "This IND submission is a key milestone in the clinical development of 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, as well as other RNA virus associated diseases."

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. Its unique mechanism of action gives AB210 a combination of anti-coagulant, immuno-modulation and anti-viral properties, and therefore the potential to be effective in addressing the pathologies caused by viral infections from multiple aspects. AB201 has previously undergone Phase 1 and Phase 2 testing in more than 700 patients, including in clinical studies for prevention of venous and arterial thrombosis, 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 and other aspects of the immune response, 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.

Investor & Media Contact:
Derek Cole
720.940.2163
derek.cole@arcabio.com

###