ARCA BIOPHARMA ANNOUNCES AB201 DEVELOPMENT PROGRAM FOR TREATMENT OF COVID-19 ASSOCIATED COAGULOPATHY

- ***AB201 (rNAPc2) is being developed as a potential treatment for COVID Associated Coagulopathy, a condition characterized by abnormal blood clotting in patients with COVID-19***
- ***Previous safety data in more than 700 patients through Phase 2 may enable more rapid development***
- ***ARCA anticipates filing an IND in the third quarter of 2020 and initiating late-stage clinical testing in the second half of this year***
- ***Prior rNAPc2 results treating Ebola and Marburg viral infections in non-human primate trials support development as treatment for RNA virus associated disease***
- ***AB201 (rNAPc2) is a potent inhibitor of tissue factor, a key driver of the viral infection process and associated inflammatory response, including virus-associated coagulopathy***

Westminster, CO, May 28, 2020 – ARCA biopharma, Inc. (Nasdaq: ABIO) today announced a new development program to evaluate AB201 (rNAPc2), a potent, selective inhibitor of tissue factor (TF), as a potential treatment for COVID-19 associated coagulopathy (CAC) and the related inflammatory response. CAC is one of the most serious adverse effects seen in COVID-19 patients. AB201 has previously undergone clinical testing through Phase 2 in more than 700 patients for other indications, generating substantial safety data, which the Company believes may enable more rapid development. ARCA anticipates filing an Investigational New Drug (IND) application with the U.S. Food and Drug Administration (FDA) in the third quarter and initiating late-stage clinical testing in the second half of this year.

TF is the protein responsible for initiating the primary or extrinsic coagulation pathway. TF has been identified as playing a central role in the inflammatory response to viral infections and in the process of viral dissemination. AB201 (rNAPc2), a single-chain, 85 amino acid, recombinant protein, 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 coagulopathic disorders in which the blood's ability to coagulate (form clots) is impaired by consumption of clotting factors (disseminated intravascular coagulation, DIC). For example, filovirus infections such as Ebola and other hemorrhagic fevers are characterized by dysregulated activation of the TF pathway, resulting in abnormal systemic coagulation and related inflammation, leading to organ failure and mortality. Recent mechanistic discoveries, as well as data from studies in non-human primates (NHPs) given lethal doses of Ebola or Marburg filoviruses demonstrating 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. Collectively, the Company believes these observations provide a strong rationale for investigating AB201 as a treatment for COVID-19, the disease caused by SARS CoV-2 virus.

COVID-19 disease is associated with a significant incidence of coagulation-related adverse events, including stroke, MI (i.e., heart attack), pulmonary emboli, and disseminated intravascular coagulation (DIC), a condition in which small blood clots develop throughout the bloodstream. A commonly used biomarker for assessing coagulation activation is a D-dimer test, which is elevated in approximately 50% of hospitalized COVID-19 patients and is directly associated with adverse clinical outcomes. In Ebola or Marburg NHP models, AB201 inhibited the DIC process, as measured by lowered D-dimer levels, which the Company believes provides further support for its therapeutic potential for CAC. The Company believes the efficacy of AB201 against COVID-19 disease may not be affected by potential mutations of the SARS CoV-2 virus, would be additive with therapeutics inhibiting virus-cell binding or viral RNA polymerase, and could be effective against other coagulopathy-associated viruses.

Dr. Wolfram Ruf, Scientific Director of the Center for Thrombosis and Hemostasis at the Johannes Gutenberg University Medical Center Mainz, Germany, and Professor at Scripps Research, La Jolla, CA, commented, “Our research, combined with the accumulating evidence on the clinical importance of large and small vessel thromboses in the COVID-19 infected patients, points to a potentially important role for the tissue factor pathway in viral infection, inflammatory response and the development of coagulopathy. With its properties in modulating the TF pathway and the evidence from its prior development, rNAPc2 has the potential to be a uniquely beneficial therapy for patients with COVID-19.”

Dr. Michael Bristow, ARCA’s President and Chief Executive Officer, who is also an American Heart Association (AHA) funded COVID-19 investigator, commented, “During this global health crisis, we believe it is important to rapidly and collaboratively evaluate multiple technologies to address COVID-19 and the associated pathologic host responses. The combination of anticoagulation, anti-inflammatory effects and antiviral activity have the potential to make AB201 a unique therapeutic to treat patients afflicted with COVID-19 while vaccine development is underway and for patients for whom a vaccine is not effective. We believe this therapeutic approach may also have potential to address future outbreaks of diseases related to other RNA viruses.”

Next Steps:

- The Company anticipates filing an IND application for AB201 as a potential treatment for COVID-19 with the FDA in the third quarter of this year.

- In collaboration with the Colorado Prevention Center, the University of Colorado's Academic Research Organization directed by Marc Bonaca, MD, a vascular and anti-coagulation clinical trialist, a Phase 2B/3 clinical trial protocol is being developed for hospitalized COVID-19 patients with elevated D-dimer levels.

- Pending FDA concurrence and obtaining trial funding, ARCA estimates initiating late-stage clinical testing of AB201 in the second half of 2020.

Dr. Bonaca commented, "The thrombotic complications of COVID-19 are severe and stem directly from viral activity and vascular inflammation. By targeting tissue factor and the extrinsic pathway, AB201 may offer a unique approach that could simultaneously reduce the severity of the viral infection as well as reduce the risk of its thrombotic complications. The extensive Phase 2 safety experience in other diseases could enable more rapid development via a Phase 2B-Phase 3 adaptive program."

AB201 is manufactured using a proven process that enables production at commercial scale, should clinical testing provide sufficient evidence of efficacy to seek regulatory approval.

About the Novel Coronavirus SARS-CoV-2 (and COVID-19 Disease)
SARS-CoV-2 is a new coronavirus identified in late 2019 and belongs to a family of enveloped RNA viruses that include Middle East Respiratory Syndrome (MERS) and Severe Acute Respiratory Syndrome (SARS-CoV), both of which caused serious human infections of respiratory system. The disease caused by the SARS-CoV-2 virus has been designated COVID-19. Since this outbreak was first reported in late-2019, the virus has infected over 5.4 million people and has caused over 349,000 reported deaths (as of May 27, 2020). It has been declared a pandemic by the World Health Organization. Currently there is no vaccine or curative drug therapy for COVID-19.

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 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 the ability of ARCA's financial resources to support its operations through the end of the third quarter of 2020, potential future development plans for AB201 and Gencaro, the expected features and characteristics of AB201 or Gencaro, including the potential for AB201 to treat COVID-19/CAC, the potential for genetic variations to predict individual patient response to Gencaro, Gencaro's potential to treat AF, future vaccines and/or treatment options for patients with COVID-19, 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 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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