AB201 Development as a Potential Treatment for COVID-19 Receives U.S. FDA Fast Track Designation

- Development addresses need for treatments for patients hospitalized with COVID-19 whether vaccines are available or not
- AB201 is the only novel compound being developed for COVID Associated Coagulopathy
- Initiation of ASPEN-COVID-19 Phase 2b clinical trial anticipated in December
- Topline trial data anticipated Q2 2021

Westminster, CO, November 23, 2020 – ARCA biopharma, Inc. (Nasdaq: ABIO), a biopharmaceutical company applying a precision medicine approach to developing genetically targeted therapies for cardiovascular diseases, today announced that the U.S. Food and Drug Administration (FDA) has designated as a Fast Track development program the investigation of AB201 as a potential treatment for COVID-19. The Company intends to initiate a Phase 2b clinical trial (ASPEN-COVID-19) of AB201 in approximately 100 patients hospitalized with COVID-19 in December 2020, with topline trial data anticipated in the second quarter of 2021.

According to the FDA's Fast Track Guidance document, Fast Track programs are designed to facilitate the development and expedite the review of new drugs that are intended to treat serious or life-threatening conditions and that demonstrate the potential to address unmet medical needs.

"Fast Track designation for the AB201 development program is an important acknowledgement of the critical need for treatments for hospitalized COVID-19 patients, whether effective vaccines are approved and available or not" said Dr. Michael Bristow, ARCA's President and Chief Executive Officer, who is also an American Heart Association (AHA) funded COVID-19 investigator. "We believe AB201's combination of anticoagulant, anti-inflammatory and antiviral effects may favorably impact clinical recovery of patients hospitalized with COVID-19 and look forward to beginning the ASPEN-COVID-19 trial to evaluate AB201's potential efficacy in this patient population."

Fast Track drug development designation is included in the FDA Modernization Act of 1997 (FDAMA) as a formal process to enhance interactions with the FDA during drug development. A drug development program with Fast Track designation would be eligible for consideration for some or all of the following programs for expediting development and review: scheduled meetings to seek FDA input into development plans, priority review of the New Drug Application (NDA), the option of submitting portions of an NDA prior to submission of the complete application and potential accelerated approval. ARCA believes that AB201 is the only anticoagulant class new chemical entity in development for COVID-19 that has a Fast Track designation.

About AB201
AB201 is a small recombinant protein being developed as a potential treatment for RNA virus-associated diseases, 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 AB201 a combination of anti-coagulant, anti-inflammatory and anti-viral properties, and therefore the potential to be effective in addressing the impact of viral infections from multiple pathways. 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 pharmacogenetic treatment for atrial fibrillation in patients with heart failure. 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, the expected features and characteristics of AB201, AB201's potential to treat COVID-19, CAC or any other RNA virus associated disease, whether AB201 is the only anticoagulant class new chemical entity in development for COVID-19 that has a Fast Track designation and future treatment options for patients with COVID-19. 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 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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