



ARCA biopharma Announces Submission of PCT Patent Application for the Treatment of Coronavirus Infection and Associated Coagulopathy with rNAPc2

Westminster, CO, August 9, 2021 – [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 submitted a Patent Cooperation Treaty (PCT) patent application, following on previously submitted provisional patent applications, for the use of the Company’s developmental drug rNAPc2 to treat patients hospitalized with COVID-19.

The patent is based on novel research discoveries from the laboratory of Univ.-Prof. Dr. Wolfram Ruf, at the Center for Thrombosis and Hemostasis (CTH) of the University Medical Center Mainz, Germany. The Company believes that this patent, if issued, could potentially provide effective market exclusivity for rNAPc2 in certain countries for the treatment of patients with SARS-CoV-2 infection and associated coagulopathy into approximately 2040, if rNAPc2 is further developed and approved for this indication. The Company plans to pursue related patent protection in foreign jurisdictions as appropriate.

The [Patent Cooperation Treaty](#) (PCT) is an international treaty with more than 150 Contracting States. The PCT makes it possible to seek patent protection for an invention simultaneously in a large number of countries by filing a single “international” patent application instead of filing several separate national or regional patent applications. The granting of patents remains under the control of the national or regional patent offices in what is called the “national phase”.

rNAPc2 is a small recombinant protein being developed as a potential treatment for serious viral infections, initially focusing on COVID-19. rNAPc2 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 rNAPc2 a combination of anti-coagulant, anti-inflammatory and potential anti-viral properties, and therefore the Company believes it may be effective in addressing the impact of viral infections from multiple pathways. rNAPc2 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 SARS-CoV-2 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 including research from Dr. Ruf’s laboratory 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 rNAPc2 may have important antiviral and anti-inflammatory activity in addition to its anticoagulant effects.

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 rNAPc2 as a potential treatment for diseases caused by RNA viruses, initially focusing on COVID-19. The U.S. FDA has granted Fast Track designation to the rNAPc2 development program, currently in Phase 2b clinical testing and an Orphan Drug designation for the use of rNAPc2 for the treatment of Ebola. ARCA is also developing GencaroTM (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 potential future development plans for rNAPc2, the expected features and characteristics of rNAPc2, the anticipated development timeline for rNAPc2, rNAPc2's potential to treat COVID-19, or any other RNA virus associated disease, whether rNAPc2 is the only anticoagulant class new chemical entity in development for COVID-19 Associated Coagulopathy and the potential future treatment options and needs 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 rNAPc2 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, 2020, 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

###