

# ARCA biopharma Announces rNAPc2 COVID-19 Patent Assignment Agreement

• Provides exclusive world-wide patent rights to the use of rNAPc2 as a potential treatment for COVID-19 and other indications

Westminster, CO, July 7, 2021 – ARCA biopharma, Inc. (Nasdaq: ABIO) today announced it has entered into a patent assignment agreement with the <u>University Medical Center of Johannes Gutenberg University Mainz</u>, Germany. Under the agreement, ARCA receives exclusive worldwide patent rights to the use of rNAPc2 as a potential treatment for COVID-19, and other indications, based on the research and discoveries from the laboratory of Univ.-Prof. Dr. Wolfram Ruf, the Scientific Director and Alexander von Humboldt Professor at the Center for Thrombosis and Hemostasis (CTH) of the University Medical Center Mainz.

rNAPc2 is a recombinant protein therapeutic being developed by ARCA as a potential treatment for COVID-19 and other severe viral infections. <u>ASPEN-COVID-19</u> is an on-going Phase 2b clinical trial evaluating rNAPc2 as a potential treatment for patients hospitalized with COVID-19. The <u>U.S. Food and Drug Administration (FDA)</u> designated the investigation of rNAPc2 as a potential treatment for COVID-19 as a Fast Track development program.

Univ.-Prof. Dr. Ruf commented, "We believe our research, combined with the accumulating evidence on the clinical importance of large and small vessel thromboses in 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. Based on its unique modulation of the tissue factor pathway and the evidence from its prior development, we believe rNAPc2 has the potential to be a beneficial therapy for patients with COVID-19."

Dr. Michael Bristow, ARCA's President and Chief Executive Officer, commented, "We are delighted to continue our collaboration with Dr. Ruf and the researchers at the University Medical Center Mainz to advance the development of rNAPc2 as a potential treatment for patients hospitalized with COVID-19. Despite the availability of vaccines and with the emergence of multiple variants, patients around the world continue to experience severe cases of COVID-19 that require hospitalization. We believe rNAPc2's combination of anticoagulant, anti-inflammatory and antiviral properties give it the potential to be effective in addressing the impact of COVID-19 from multiple pathways. As a potential therapeutic aimed at a host response to a disease syndrome, we believe rNAPc2 has therapeutic potential to be used for future viral outbreaks beyond the current pandemic, even as safe and effective vaccines for SARS-CoV-2 are successfully deployed."

Under the Agreement with the University Medical Center Mainz, ARCA also obtains an option to acquire world-wide patent rights to discoveries related to the use of rNAPc2 as a potential

therapeutic for auto-immune disorders such as systemic lupus erythematosus, that involve the presence of anti-phospholipid antibodies linked to tissue factor, as well as the option to acquire patent rights for discoveries relating to other therapeutic uses of rNAPc2. Under the Agreement, ARCA has potential upfront and milestone obligations that could total approximately €1.6 million and royalty obligations in the low single digit range, if rNAPc2 receives regulatory approval and is commercialized.

### **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 severe viral infections, initially focusing on COVID-19. The U.S. FDA has granted Fast Track designation to the rNAPc2 development program, currently in Phase 2 clinical testing. ARCA is also developing Gencaro<sup>TM</sup> (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 <a href="www.arcabio.com">www.arcabio.com</a> or follow the Company on LinkedIn.

# **About the University Medical Center of the Johannes Gutenberg University Mainz**

The University Medical Center of the Johannes Gutenberg University Mainz is the only medical institution of supra-maximum supply in the German state of Rhineland-Palatinate and an internationally recognized science location. Medical and scientific specialists at 60 clinics, institutes and departments work interdisciplinarily to treat more than 350,000 patients per year. Highly specialized patient care, research and teaching are inseparably intertwined. Around 3,400 medicine and dentistry students as well as more than 600 future medical, commercial and technical professionals are trained in Mainz. With a workforce of approximately 8,500 colleagues the University Medical Center Mainz is one of the largest employers in the region and an important driver of growth and innovation. Find more information online at <a href="https://www.unimedizin-mainz.de">www.unimedizin-mainz.de</a>.

#### **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 and Gencaro, the expected features and characteristics of rNAPc2 or Gencaro, including the potential for rNAPc2 to treat COVID-19, 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 rNAPc2 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, 2020, and subsequent filings. ARCA disclaims any intent or obligation to update these forward-looking statements.

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