



**PRESS RELEASE**  
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**ARCH BIOPARTNERS' LEAD ANTI-BACTERIAL DRUG CANDIDATE  
AB569 TO ENTER INVESTIGATOR-SPONSORED PHASE I HUMAN  
TRIAL**

Toronto, Canada - Arch Biopartners Inc., (Arch or the Company) (TSX Venture: ARCH and OTCBB: ACHFF) a portfolio-based biotechnology company, today announced that the Cincinnati Veterans Affairs Medical Center (CVAMC) will conduct an investigator initiated Phase I human trial to evaluate the safety and pharmacokinetic profile of AB569, the Company's inhalation drug candidate for treating antibiotic-resistant bacterial infections in the lungs.

The World Health Organization has declared antibiotic resistance to be one of the biggest threats to global health and development today. According to WHO, while there are new antibiotics currently in development, none are expected to be effective against the most dangerous forms of antibiotic-resistant bacteria. The Company's AB569 is a non-antibiotic drug that could be a viable alternative or adjunct therapy to current standard of care antibiotics.

AB569 consists of two active ingredients, sodium nitrite and ethylenediaminetetraacetic acid (EDTA) that have potent, synergistic bactericidal properties. AB569 has a novel mechanism of action that differs from that of antibiotics and was invented by Dr. Daniel Hassett at the University of Cincinnati College of Medicine.

In pre-clinical studies, Dr. Hassett and his team demonstrated the potency of acidified sodium nitrite and EDTA in killing drug resistant bacteria such as *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Burkholderia cepacia* under both aerobic and anaerobic planktonic (free-living) and biofilm (surface-attached) conditions. These bacteria are among the most common pathogens to chronically infect the lungs of patients with chronic obstructive pulmonary disease (COPD) or cystic fibrosis (CF).

"My lab has shown AB569 to be very efficacious at killing all of the Gram-negative and Gram-positive bacteria strains we have collected over the years from numerous hospital patients, many of which are highly resistant to antibiotics. AB569 has demonstrated it can kill all of these bacteria in our in vitro studies at concentrations that do not harm human cells. Furthermore, we have discovered that none of these pathogens are capable of developing resistance to AB569," said Dr. Hassett.

Dr. Ralph Panos, Chief of Medicine at CVAMC and world-renowned COPD expert, is the lead investigator of the trial. Arch is funding the study, contributing AB569 inhalation kits and other materials to support the trial.

“This is an important trial to show clinicians that AB569 is safe for use in humans. Once we establish that, we look forward to transitioning the AB569 program into a Phase II trial at CVAMC where we can test the drug’s efficacy in treating antibiotic resistant infections in the lungs of patients with COPD. Greater than 40% of patients at the CVAMC have COPD and AB569 has the potential to solve a major clinical challenge we currently face,” said Dr. Panos.

Clinical investigators at the CVAMC will evaluate single administration of nebulized AB569 in normal participants. The Phase I trial has been designed to determine the pharmacokinetic profile of plasma nitrite and nitrate metabolites, exhaled nitric oxide and circulating hemoglobin after a single inhalation of AB569. In addition, the trial also aims to determine the tolerance of nebulized AB569 in three escalating doses of acidified sodium nitrite and EDTA.

“At a time where new treatments are urgently needed to kill highly problematic, antibiotic-resistant bacteria, moving AB569 into a Phase I human trial at CVAMC is a major milestone for the program and the development of Arch Biopartners,” said Claude Allary, a board member of Arch.

Dr. Hassett’s team has also shown the potential of AB569 to be used for treating drug resistant urinary tract infections and as an effective catheter lock solution to inhibit infection and destroy bacterial biofilms commonly observed in dialysis patients.

The Company’s sponsorship of the human trial application to the Internal Review Board of CVAMC and University of Cincinnati was facilitated through the Cincinnati Education and Research for Veteran’s Foundation.

As a result of the approved Phase I human trial at CVAMC, Arch has initiated the GMP manufacturing of the AB569 drug product that is required for the trial. It is expected that the Phase I trial will be ready to start once the drug kits are completed and delivered to CVAMC.

#### **Notes for Editors:**

#### **About AB569 and Anti-biotic resistant airway infections in COPD and CF patients**

AB569 was invented by Dr. Daniel Hassett, Professor at the University of Cincinnati College of Medicine, to treat antibiotic resistant bacterial lung infections, which is a significant problem for patients with either CF or COPD. AB569 is also a candidate treatment for antibiotic resistant urinary tract infections, skin infections and as a catheter lock solution. The University of Cincinnati has exclusively licensed AB569 to Arch.

AB569, as a bactericidal compound, constitutes an innovative potential treatment for dealing with pulmonary bacterial infections, some of which are resistant to all 26 approved antibiotics in the United State alone. In pre-clinical studies, AB569 has demonstrated significant ability to kill many types of Gram-negative and Gram-positive bacteria.

Arch has received orphan drug designation for AB569 from the U.S. Food and Drug Administration for the treatment of CF patients with *Pseudomonas aeruginosa* infections. Arch has also received an orphan medicinal product designation from the European Medicines Agency for the treatment of CF patients.

CF patients are predisposed to bacterial lung infections due to abnormal mucus production in the lungs and airways. In particular, *Pseudomonas aeruginosa* infects 40% of CF patients between the ages of 6 and 10 years of age. By the age of 17, the frequency of infection increases to 60% and reaches approximately 75% of all CF patients between the ages of 25 and 34.

The mucoid form of *P. aeruginosa* is a very challenging infection to treat due to its high resistance to both antibiotics and phagocyte-mediated killing. Once patients present with the mucoid form of *P. aeruginosa*, their overall lung function precipitously declines, resulting in a poor overall clinical prognosis.

Like CF patients, people with COPD have compromised innate immune systems and respiratory conditions that are vulnerable to chronic bacterial infections that are often refractory to conventional antibiotic regimens.

COPD is a major health problem worldwide and its prevalence is increasing (over 325,000,000 patients world-wide), ranked by the World Health Organization as the third leading cause of death. COPD is a general term to describe progressive lung diseases which includes chronic bronchitis, emphysema, and non-reversible asthma. Most cases are caused by inhaling pollutants, predominantly from smoking or exposure to lung pollutants in highly polluted cities around the world as well as the workplace.

### **About Arch Biopartners**

Arch Biopartners Inc. is focused on the development of innovative technologies that have the potential to make a significant medical or commercial impact. Arch works closely with the scientific community, universities and research institutions to advance and build the value of select preclinical technologies, develop the most promising intellectual property, and create value for its investors.

Arch has established a diverse portfolio that includes AB569, a potential new treatment for antibiotic resistant bacterial infections; Metablok, a potential treatment for inflammation, sepsis and cancer metastasis; MetaMx, which targets elusive brain tumor initiating cells; and, 'Borg' peptide coatings that increase corrosion resistance and decrease biofilm on various medical grade metals and plastics.

For more information on Arch Biopartners, other public documents Arch has filed on SEDAR and its technologies including, please visit [www.archbiopartners.com](http://www.archbiopartners.com)

The Company has 54,849,679 common shares outstanding.

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## **Forward-Looking Statements**

All statements, other than statements of historical fact, in this news release are forward looking statements that involve various risks and uncertainties, including, without limitation, statements regarding the future plans and objectives of the Company. There can be no assurance that such statements will prove to be accurate. Actual results and future events could differ materially from those anticipated in such statements. These and all subsequent written and oral forward-looking statements are based on the estimates and opinions of management on the dates they are made and are expressly qualified in their entirety by this notice. The Company assumes no obligation to update forward-looking statements should circumstances or management's estimates or opinions change.

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