



**PRESS RELEASE  
FOR IMMEDIATE DISTRIBUTION  
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**ARCH BIOPARTNERS' GMP MANUFACTURING OF AB569  
PROGRESSES TO FINAL PRODUCTION STAGE**

Toronto, Canada - Arch Biopartners, Inc., (Arch or the Company) (TSX Venture: ARCH and OTCBB: ACHFF) today announced that the good manufacturing practice (GMP) production campaign for AB569 has advanced to the GMP glass vial filling stage. AB569 is the Company's inhalation drug candidate for treating antibiotic-resistant bacterial infections in the lungs of cystic fibrosis (CF) and chronic obstructive pulmonary disease (COPD) patients as well as many other indications.

AB569 is a potential stand alone or complementary treatment to existing and emerging standard of care therapies for CF and COPD patients that have reduced lung function due to multi-drug resistant bacterial infections.

***Manufacturing of AB569: update***

AB569 is mainly composed of two compounds: ethylenediaminetetraacetic acid (EDTA) and sodium nitrite, which are already approved by the U.S. Food and Drug Administration (FDA) for use in humans in other medical applications.

The GMP manufacturing process and the terminal sterilized glass vial filling campaign for AB569 is being led by Dalton Pharma Services (Dalton). Dalton is initiating the GMP glass vial fill of three varying dose formulations of sodium nitrite followed by EDTA. These vials will then be packaged by Dalton into clinical drug kits to enable the start of the Phase I safety trial for AB569 at the Cincinnati Veterans Affairs Medical Center (CVAMC) at the end of this year or early January 2018.

Arch management intends to provide updates regarding the delivery date of the clinical drug kits to CVAMC and the start date of the Phase I safety trial as the glass vial filling stage nears completion.

***Upcoming Phase I investigator Initiated Trial***

CVAMC will conduct an investigator initiated Phase I human trial to evaluate the safety and pharmacokinetic profile of AB569

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 the AB569 inhalation clinical drug kits produced by Dalton and other materials to support the trial.

Dr. Pano's clinical team 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.

Following the successful completion of the Phase I study, the clinical team at CVAMC in association with the University of Cincinnati College of Medicine will transition the AB569 program into a Phase II trial to test the drug treatment's efficacy in treating chronic *Pseudomonas aeruginosa* (*P. aeruginosa*) infections in COPD patients.

### ***Background to AB569 for antibiotic resistant airway infections***

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, COPD or ventilator associated pneumonia, as well as burn, diabetic and blast wounds. AB569 is also a candidate treatment for antibiotic resistant urinary tract infections and skin infections. The University of Cincinnati has exclusively licensed AB569 to Arch.

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

*P. aeruginosa* affects the majority of adult CF patients and often infects patients from childhood onward. Arch has received orphan drug designation for AB569 from the FDA for the treatment of CF patients with *P. aeruginosa* infections. Arch has also received an orphan medicinal product designation from the European Medicines Agency for the general treatment of CF patients.

CF patients are predisposed to bacterial lung infections due to abnormal mucus production in the lungs and airways. In particular, *P. 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 65% 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.

Likewise, people with COPD have compromised innate immune systems and respiratory conditions that are vulnerable to chronic bacterial infections including *P. aeruginosa* 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 Dalton**

Dalton Chemical Laboratories Inc. o/a Dalton Pharma Services is a Health Canada approved and FDA registered cGMP contract service provider of integrated chemistry, drug development and manufacturing services to the pharmaceutical and biotechnology industries. Dalton brings 30 years of experience to their client's projects and emphasize quality, speed and flexibility.

Dalton can accelerate a drug development program by integrating process development, [cGMP API manufacturing](#) and sterile or solid finished dose manufacturing all at a single location. For Dalton's full range of in-house services including [cGMP sterile fill/finish services](#) please visit [www.dalton.com](http://www.dalton.com).

CMO 2016 and 2017 Leadership Awards in the categories of Quality, Reliability, Capabilities, Expertise, Compatibility and Development from Life Science Leader reflects Dalton's ongoing commitment to their clients, peers and the business community. In 2016 Dalton was certified as "A Great Place to Work."

## **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 55,299,679 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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