25 August 2025

Independent U.S. In Vivo Study Demonstrates ArtemiC™ Efficacy in Viral Inflammatory Model

Highlights:

- An independent in vivo study conducted by the University of South Florida (USF) demonstrated up to 85% improvement over the control group in a viral inflammatory mouse model treated with ArtemiC™
- ArtemiC™ is the U.S. OTC unlicensed drug brand name of CimetrA®, developed as a nano-formulated oral therapy for Acute Respiratory Distress Syndrome (ARDS) and related cytokine-driven disorders
- Significant reductions in viral load and cytokine-induced inflammation observed in lung and brain tissue.
- Supports ArtemiC™ mechanism of action as a nano-formulated immunomodulator without immunosuppression.
- Study conducted independently by AMC Pharma USA, without funding or direction from Argent BioPharma.
- Ongoing outreach to U.S. health policy stakeholders exploring safe, non-immunosuppressive treatments for viral-induced ARDS and autoimmune inflammatory conditions.

Independent U.S. In Vivo Study on ArtemiC™

Argent BioPharma Ltd. (ASX: RGT) is pleased to announce the results of an independent in vivo study evaluating the efficacy of **ArtemiC™**, the USA OTC Unlicensed Drug Brand name of CimetrA®, its lead immunomodulatory therapeutic, in a severe viral inflammatory model **targeting Acute Respiratory Distress Syndrome (ARDS).**

The in vivo study on **ArtemiC™** was conducted independently and fully financed by **AMC Pharma USA** in collaboration with the Botanical Medicine Research and Education Consortium (BMREC) at the **University of South Florida** (USF) in Tampa, Florida. Completed in April 2025 and published on 20th August 2025, the study assessed the therapeutic impact of ArtemiC™ in K18-hACE2 transgenic mice (20 mice per group) within a severe viral inflammatory model. The strength of these results provides a robust scientific foundation for AMC Pharma's commercial strategy, supporting anticipated future orders in the United States and other international territories under its existing distribution agreements.

Treated animals demonstrated a survival rate of **up to 85%**, compared with **0% in the untreated control group (p<0.001)**, highlighting the profound efficacy of **ArtemiC™** in a lethal infection model. The therapy not only achieved a significant **reduction of viral load in both lung and brain tissue**, but also markedly suppressed cytokine-driven inflammatory injury, a key driver of morbidity. Systemic treatment with **ArtemiC™** enhanced overall antiviral efficacy and extended life expectancy, yielding an additional **20–40% survival advantage** in treated cohorts. Furthermore, ArtemiC™ effectively mitigated the cytokine storm triggered in K18-hACE2 mice subjected to a severe viral inflammatory challenge, thereby reinforcing its proposed **mechanism of action as a targeted anti-inflammatory intervention in acute**, hyperinflammatory disease conditions.

About ArtemiC™

ArtemiC™ is the U.S. OTC unlicensed drug brand name of **CimetrA®**, Argent BioPharma's lead nano-formulated immunomodulator, developed for the treatment of both acute inflammatory responses and chronic autoimmune conditions. The formulation contains two active pharmaceutical ingredients delivered through a proprietary oromucosal nanoparticle system, designed to target key cytokine pathways including IL-32, NF-κB, and p38 MAPK, while simultaneously upregulating protective cellular mechanisms such as HO-1.

ArtemiC™ is being developed as a targeted therapy for **Acute Respiratory Distress Syndrome (ARDS)**. It has demonstrated a strong safety profile and therapeutic benefit across multiple completed studies, without any adverse events. Phase II and Phase IIb clinical trials showed clinically meaningful improvements in respiratory and inflammatory markers. Preclinical toxicology programs confirmed excellent tolerability, while real-world data from early-access use further support its rapid and well-tolerated effect

Roby Zomer, Managing Director and CEO, Argent BioPharma, commented:

"*These independent in vivo data, generated in the United States by respected academic and clinical teams, validate ArtemiC™'s immunological mode of action. The efficacy in controlling viral-driven inflammation without immune suppression reinforces our clinical and regulatory strategy for treating severe infections, ARDS"*

"We are also pleased to confirm that our American program remains active. We have stayed committed to delivering these trial results because both our team and our partners at AMC believe we have developed something that should be made available to Americans and people worldwide. We are advancing registration in additional territories and look forward to sharing more soon. I would also like to thank our ***U.S. representative, Mr. Daniel Erdman****, whose leadership has been instrumental in coordinating the program, securing these trial results, and driving the continued development of ArtemiC™ in the United States.*

Brent Yessin, Esq., AMC Pharma USA, commented:

"We believe the current administration of RFK Jr. would welcome an alternative for the 40–50% of Americans reluctant to take vaccines. Our team is working to advance regulatory support for ArtemiC™, and these data strengthen the case for its broader deployment. In parallel, we are awaiting approval by COFEPRIS to launch ArtemiC™ nationwide in Mexico ahead of the flu season, providing timely access to a safe, inflammation-modulating therapy for communities in need"

The Company notes that the U.S. study was initiated, funded, and conducted independently by AMC Pharma USA, without scientific or financial input from Argent BioPharma.

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Authorised for release by the board of directors, for further information please contact:

Argent BioPharma
Roby Zomer
CEO & Managing Director
+61 8 6555 2950
info@argentbiopharma.com

Argent BioPharma
Rowan Harland
Company Secretary
+61 8 6555 2950
info@argentbiopharma.com

Argent BioPharma Ltd. (ASX: RGT) is a clinical-stage biopharmaceutical company developing nano-engineered medicines that restore balance between the nervous and immune systems. Its lead candidates, CannEpil® and CimetrA®, target drug-resistant epilepsy and cytokine-driven inflammatory and autoimmune disorders, respectively. The Company's proprietary delivery platforms are designed to improve penetration across the blood–brain and alveolar–capillary barriers, enabling differentiated efficacy and supporting composition-of-matter protection. With EU-GMP manufacturing, advancing late-stage clinical programs, and a unified Neuro-Immune Modulatory platform, Argent BioPharma is building a high-impact pipeline with a clear focus on urgent unmet needs in CNS and systemic inflammation.

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Annex 1

Study Overview – University of South Florida / AMC Pharma USA

Study Title: *Evaluation of a Multi-Compound Oral Therapy in a Murine Model of SARS-CoV-2-Induced Cytokine Storm*

Conducting Institutions:

- Botanical Medicine Research and Education Consortium (BMREC),
  University of South Florida (USF), Tampa, FL, USA
- In collaboration with AMC Pharma USA, distributor of ArtemiC™ in the United States.

Study Leadership:

- Principal Investigator: Dr. Mark S. Kindy, PhD
  Professor of Molecular Pharmacology & Physiology,
  Director of BMREC, University of South Florida

Date of Completion: April 2025

Study Design Summary:

An *in vivo* efficacy study conducted in 20 K18-hACE2 transgenic mice (20 mice per group) infected with a lethal dose of SARS-CoV-2. The mice were administered an oral multi-compound formulation aligned with **ArtemiC™** (OTC brand name of CimetrA®) and were monitored for survival, viral load, and inflammatory markers compared to untreated controls.

Objectives:

- To assess the therapeutic impact of ArtemiC™ in mitigating inflammatory response and mortality in severe COVID-19-like infection.
- To quantify changes in viral burden across major organs (lung, brain).
- To evaluate modulation of cytokine storm-related damage.

Key Results:

1. The systemic treatment of these mice with ArtemiC™ resulted in enhanced antiviral efficacy and yielded an increased life expectancy of about 20-40% survival.
2. In lethally infected mice, the treatment showed profound inhibition of SARS-CoV-2 replication in both the lung and brain, synergistically improving survival rates up to 85% compared to untreated mice ($p<0.001$).
3. The therapy effectively reduced clinical severity scores, virus-induced tissue damage, and viral distribution compared to those in animals treated with monotherapies.
4. Additionally, the treatment with ArtemiC™ reduced the cytokine storm elicited by the SARS-CoV-2 infected K18-hACE2 transgenic mice.
5. These findings suggest that therapy with ArtemiC™ contributes to alleviated morbidity and mortality, which can serve as a basis for the design of clinical studies in the treatment of COVID-19 patients, as well as other viral infections.

Argent BioPharma ltd
Suite 1, 295 Rokeby Road
Subiaco, WA 6008, Australia

+61 8 6555 2950
info@argentbiopharma.com

Disclosure:
The study was designed, funded, and executed independently by AMC Pharma USA and USF, without involvement from Argent BioPharma Ltd. in design, protocol, or data handling.

About the author and the laboratory. Dr. Mark S. Kindy, PhD is the Director of the Botanical Medicine Research and Education Consortium (BMREC) at the University of South Florida in Tampa, FL. His lab focuses on the impact of chronic inflammation in neurological and neurodegenerative diseases (stroke, Alzheimer's disease, Parkinson's disease, traumatic brain injury, etc.), as well as cardiovascular disease and cancer. USF is a public research university with 50,000 students. USF Health receives roughly $300M of healthcare research grants annually.

Argent and AMC Pharma USA have worked with USF and its researchers for more than two years and have begun a study on the prophylactic effects of ArtemiC™ on infected animals.

Argent BioPharma ltd
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