

Arch Biopartners Announces Alberta Health Services Approval to Proceed with Phase II Trial for LSALT Peptide Targeting Cardiac Surgery-Associated Acute Kidney Injury (CS-AKI)

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TORONTO, Sept. 11, 2024 (GLOBE NEWSWIRE) -- **Arch Biopartners Inc.**, (“Arch” or the “Company”) (TSX Venture: ARCH and OTCQB: ACHFF), announced today that Alberta Health Services (AHS) has approved the Phase II trial for LSALT peptide targeting the prevention and treatment of cardiac surgery-associated acute kidney injury (CS-AKI).

The clinical team at the University of Calgary Cumming School of Medicine is now completing final preparations and training to enable the start of patient recruitment in September. University Health Network and Unity Health Toronto are also working on final ethics and hospital approvals to start patient recruitment at Toronto General Hospital and St. Michael’s Hospital, respectively.

The trial continues to recruit patients at five clinical sites in Turkey.

About the CS-AKI Phase II Trial

The CS-AKI Phase II trial is an international, multi-center, randomized, double-blind, placebo-controlled study of LSALT peptide with a recruitment target of 240 patients.

The primary objective of the trial is to evaluate the percentage of subjects with acute kidney injury (AKI) within seven days following on-pump (heart-lung machine) cardiac surgery, as defined by the KDIGO (Kidney Disease: Improving Global Outcomes) criteria.

Details of the Phase II trial, entitled “**Phase 2 Global, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study of LSALT peptide for the Prevention or Attenuation of Acute Kidney Injury (AKI) in Patients Undergoing On-Pump Cardiac Surgery**” can be viewed at clinicaltrials.gov.

CS-AKI and LSALT peptide

CS-AKI is often caused by ischemia-reperfusion injury (IRI) which reduces blood flow (ischemia) and oxygen to the kidney, causing kidney cell damage. When blood flow is restored (reperfusion), inflammation is triggered, exacerbating injury to the kidney. There is no therapeutic treatment available in the market today that prevents acute kidney injury of the type commonly experienced by on-pump cardiac surgery patients. In the worst cases of AKI, the kidneys fail, requiring kidney dialysis or kidney transplant for survival.

LSALT peptide is the Company’s lead drug candidate for preventing and treating inflammation injury in the kidneys, lungs and liver. The drug targets the dipeptidase-1 (DPEP1) pathway and has been shown by Arch scientists and their collaborators to prevent **IRI to the kidneys in pre-clinical models (video)**, providing the scientific rationale for Arch to use LSALT peptide in this CS-AKI trial. Details of their findings were published in the journal **Science Advances**, titled “**Dipeptidase-1 governs renal inflammation during ischemia reperfusion injury**” by Lau et. al. and can be found along with the latest **peer-reviewed publications** about DPEP1 and LSALT peptide at the Company’s website.

Incidence of CS-AKI

Acute kidney injury is a common complication in patients following coronary artery bypass grafting (CABG) and other cardiac surgeries, including on-pump surgeries which increase the risk of AKI. The reported prevalence of CS-AKI is up to 30% and is independently associated with an increase in morbidity and mortality.

About Arch Biopartners

Arch Biopartners Inc. is a late-stage clinical trial company focused on preventing inflammation and acute organ injury. The Company is developing a platform of new drugs to prevent inflammation in the kidneys, liver and lungs via the dipeptidase-1 (DPEP1) pathway, addressing common injuries and diseases where organ inflammation remains an unmet need.

For more information on Arch Biopartners’ science and drug platform, please visit: www.archbiopartners.com/our-science

For investor information and other public documents the company has also filed on SEDAR+, please visit

www.archbiopartners.com/investor-hub

The Company has 64,650,833 common shares outstanding.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of applicable Canadian securities laws regarding expectations of our future performance, liquidity and capital resources, as well as the ongoing clinical development of our drug candidates targeting the dipeptidase-1 (DPEP-1) pathway, including the outcome of our clinical trials relating to LSALT peptide (Metablok), the successful commercialization and marketing of our drug candidates, whether we will receive, and the timing and costs of obtaining, regulatory approvals in Canada, the United States, Europe and other countries, our ability to raise capital to fund our business plans, the efficacy of our drug candidates compared to the drug candidates developed by our competitors, our ability to retain and attract key management personnel, and the breadth of, and our ability to protect, our intellectual property portfolio. These statements are based on management's current expectations and beliefs, including certain factors and assumptions, as described in our most recent annual audited financial statements and related management discussion and analysis under the heading "Business Risks and Uncertainties". As a result of these risks and uncertainties, or other unknown risks and uncertainties, our actual results may differ materially from those contained in any forward-looking statements. The words "believe", "may", "plan", "will", "estimate", "continue", "anticipate", "intend", "expect" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We undertake no obligation to update forward-looking statements, except as required by law. Additional information relating to Arch Biopartners Inc., including our most recent annual audited financial statements, is available by accessing the Canadian Securities Administrators' System for Electronic Document Analysis and Retrieval ("SEDAR") website at www.sedarplus.ca.

The science and medical contents of this release have been approved by the Company's Chief Science Officer

Neither TSX Venture Exchange nor its Regulation Services Provider (as that term is defined in the policies of the TSX Venture Exchange) accepts responsibility for the adequacy or accuracy of this release

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