Asep Medical Holdings Inc.

Asep Inc. Announces Ground-breaking A.I. Technology for Rapid Identification of Severe Sepsis and Improved Superbug Therapies

VANCOUVER, BC, June 2, 2023 (CNW) — Asep Medical Holdings Inc. ("Asep Inc." or the "Company") (CSE: ASEP) (OTCQB: SEPSF) (FSE: JJ8) announces the ground-breaking use of artificial intelligence (AI) to rapidly identify infections at increased risk of severe sepsis. The method was developed by the Hancock Lab, under the guidance of Dr. Robert E.W. Hancock, Killam Professor at the University of British Columbia (UBC), and analyzes the dysfunctional immune responses involved in sepsis to identify sets of genes that help assess whether a patient will acquire severe sepsis.

"We have harnessed AI to obtain practical outcomes in areas of high unmet medical need, including identifying severe sepsis cases. Sepsis is a severe disease responsible for one in five deaths worldwide[1] and essentially all deaths from severe COVID-19. Typically, a patient arrives in the emergency room feeling profoundly ill, with fairly non-specific symptoms. Physicians are in a 'look-and-see' game for the first 24–48 hours. But for every hour that treatment is delayed, the risk of death increases by as much as 7.6%[2], highlighting the need for rapid detection," says Dr. Hancock, Chair and CEO of Asep Inc. "Using AI, our team was able to identify sets of genes that help assess whether a patient, including those with pandemic diseases like COVID-19, will acquire severe sepsis[3,4]," continued Dr. Hancock. "In early clinical studies[3,4], the Sepset^{ER} test has worked extremely well, and our bioinformatics scientists have now applied AI to report the outcome of the test to attending physicians. We are preparing for a confirmatory clinical trial at St. Paul's Hospital in downtown Vancouver, BC, to evaluate the performance of the Sepset^{ER} test on sepsis patients."

This confirmatory clinical trial will precede a larger study to demonstrate the performance of Sepset$^{ER\ TM}$, the Company's sepsis diagnostic technology, and compare it to currently available sepsis tests in anticipation of filing a 510(k) submission with the FDA seeking clearance for the test as a medical device. Asep Inc. anticipates that the 510(k) application process will be complete in Q1 2024, and the test should be available to hospitals soon after.

AI was also used to deconvolute the extreme complexity[1] of sepsis, which has limited treatment to date. In recent clinical studies published by the Lancet Journal *EBioMedicine*[3] and the Nature Journal *Scientific Reports*[4], AI

methods were applied and proved to be 97% accurate in identifying which of the five sepsis endotypes occurred in each patient. These biomarkers also worked in the ICU, where it was shown that one endotype was particularly deadly, with a mortality rate of 46%. “Deciphering the underlying mechanisms of sepsis is key to risk assessment and devising novel treatments for sepsis,” stated Hancock. “This important observation will form the basis of a second diagnostic test in development.”

THE FIGHT AGAINST BIOFILMS

The failure of antibiotics[5] due to delayed diagnosis of sepsis, the high prevalence of recalcitrant biofilm infections and increased antibiotic resistance, compounded by declining antibiotic discovery, are also among society’s most pressing health issues. Dr. Hancock and his team have applied AI to discover a host of antimicrobial peptides (strings of a dozen or so amino acids) representing a promising new class of antibiotics[6]. Asep Inc. has adapted these AI methods to address antibiotic failure associated with biofilms, a multi-cellular growth state of bacteria adaptively resistant to conventional antibiotics[7,8].

Antibiofilm peptides offer a host of real-life applications[7], including wound bandages, sinusitis, oral rinses and antibacterial medical instrument coatings, to name a few. Dr. Hancock’s team used peptide array technology to prepare large semi-random peptide libraries created using the amino acid composition of the most active peptides. The resultant data was used with an AI technique called artificial neural networks to develop quantitative in silico models of antibiotic activity[6]. Random tests proved remarkably effective in predicting the activity of 100,000 virtual peptides. The best peptides, representing the top quartile of predicted activities, were effective against a broad array of multidrug-resistant “Superbugs” with activities that were equal to or better than four highly used conventional antibiotics, more effective than the most advanced clinical candidate antimicrobial peptide, and protective against *Staphylococcus aureus* infections in animal models. Similar methods were used to derive excellent antibiofilm peptides. Asep is preparing to take the best of these peptides to the clinic.

“We use AI daily as a valuable tool in the battle against antibiotic failure. While others are trying to figure out the complexities of AI and how it can be used in their development processes, we are already using it confidently and with amazing success in our diagnostic and therapeutic offerings. We feel that the Asep Inc. scientific team is a true leader in leveraging AI's power to improve human health,” said Dr. Evan Haney, Chief Scientific Officer of Asep Inc.

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ABOUT ASEP MEDICAL HOLDINGS INC.

Asep Medical Holdings Inc. (asepmedical.com) is dedicated to addressing the global issue of antibiotic failure by developing novel solutions for significant unmet medical needs in human medicine. The Company is a consolidation of three existing private companies, all with technology in advanced development — Sepset Biosciences Inc. (proprietary diagnostic tools to enable the early and timely identification of sepsis), ABT Innovations Inc. (broad-spectrum therapeutic agents to address multi-drug resistant biofilm infections), and SafeCoat Medical Inc. (an antimicrobial peptide, anti-fouling medical device coating technology).

Sepset Biosciences Inc. (sepset.ca) is developing a diagnostic technology that involves a patient gene expression signature that help assess the development of severe sepsis, one of the significant diseases leading to antibiotic failure, since antibiotics are the primary treatment for sepsis. Sepsis was responsible for nearly 20% of all deaths on the planet in 2017 and essentially all deaths due to COVID-19 and other pandemics. The Sepset^{ER} test is a blood-based gene expression assay that is straightforward to implement, and results are obtained in about an hour after taking a blood sample in the emergency room or intensive care unit. This proprietary diagnostic technology differs from current diagnostic tests in enabling the risk assessment for progression to severe sepsis within 60 minutes of initiating the test. Bacterial culture, the gold standard, provides results after ~15 hours but can be as long as three days. Asep Inc. believes its test will enable critical early decisions to be made by physicians regarding appropriate therapies and thus reduce overall morbidity and mortality due to sepsis.

ABT Innovations Inc.'s (abtinnovations.ca) peptide technology covers a broad range of therapeutic applications, including bacterial biofilm infections (dental, wound, sinusitis, skin, medical device infections, chronic infections, lung, bladder, ear-nose and throat, orthopaedic, etc.), anti-inflammatories, anti-infective immune-modulators and vaccine adjuvants. The company is in the pre-clinical development phase for the first three indications with promising data.

SafeCoat Medical Inc.'s (safecoatmedical.com) technology encompasses self-assembling polymers combined with conjugated antimicrobial peptides, which can be applied to various surfaces as antimicrobial and anti-fouling coatings. In particular, the invention relates to coatings that may be applied to multiple medical devices and implants and feasibility has been demonstrated in animal models. The company's expertise also encompasses the methods for manufacturing and applying these anti-bacterial coatings.

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FORWARD-LOOKING STATEMENTS —

This news release contains certain "forward-looking statements" within the meaning of such statements under applicable securities law. Forward-looking statements are frequently characterized by words such as "anticipates," "plan," "continue," "expect," "project," "intend," "believe," "anticipate," "estimate," "may," "will," "potential," "proposed," "positioned" and other similar words, or statements that certain events or conditions "may" or "will" occur. These statements include but are not limited to the successful clinical testing of our Sepsis *in vitro* diagnostic test and its intended filing for regulatory market authorization; the Company not receiving regulatory market authorization as planned or at all; the undertaking of pre-clinical studies on our lead therapeutic, with the expectation that this will lead to fast-track clinical trials; the timeframe for identification of sepsis with the company's products; the potential opportunities for the generation of revenue; the therapeutic benefits of the company's products; and other statements regarding the company's proposed business plans. Various assumptions were used in drawing conclusions or making the predictions contained in the forward-looking statements throughout this news release. Forward-looking statements are based on the opinions and estimates of management at the date the statements are made and are subject to a variety of risks including the risk that the company's products may not perform as expected; that the company may not receive the requisite regulatory market authorization or results of testing; the Company's testing of the products may not be successful and approvals may not be obtained in the estimated timelines or at all; the company may not be able to generate revenue from its products as expected or at all; the market for the company's products may not be as described in this news release; and various other risk factors identified in the Asep Medical Inc.'s prospectus dated November 9, 2021, and in the company's management discussion and analysis, available for review under the Company's profile at www.sedar.com and uncertainties and other factors that could cause actual events or results to differ materially from those projected in the forward-looking statements. Asep Medical Inc. is under no obligation and expressly disclaims any intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as expressly required by applicable law.

ENDNOTES

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