Asep Medical's Sepsis Diagnostic Technology Can Provide Improved Odds for Pediatric Appendicitis

VANCOUVER, BC, Feb. 27, 2024 /CNW/ - **Asep Medical Holdings Inc.** ("**Asep Inc.**" or the "**Company**") (CSE: ASEP) (OTCQB: SEPSF) (FSE: JJ8) is pleased to announce that its proprietary gene expression signature for sepsis can provide an improved assessment of the severity of appendicitis in children. According to Dr. Rob Stenstrom, Asep's Medical Director, "Abdominal pain is one of the most common complaints we see for children in the emergency room, and so it's important that we identify the difference between simple appendicitis and perforated appendicitis quickly and accurately."

The link between appendicitis severity and sepsis was discovered as a result of a single-centre prospective exploratory diagnostic clinical study published online in the *JAMA (Journal of the American Medical Association) Pediatrics* on February 19, 2024, in an article titled *Gene Expression Profiling in Pediatric Appendicitis*, Dhillon et al., with Asep CEO Dr. Robert Hancock as senior author.[1] Thus, the gene expression signature that is foundational to the Company's AI-based sepsis diagnostic technology, called Sepset$^{ER\ TM}$, was able to distinguish between simple appendicitis (SA) and perforated appendicitis (PA), which was found to be a much more severe sepsis condition.

According to a related editorial article by Maurizio Pacilli et al.[2], in the same issue, "SA has a mortality rate of about 0.1% while PA has a mortality risk of 5%, highlighting the need for timely and accurate diagnosis and treatment ... Dhillon et al. aimed to identify blood-based biomarkers for use as clinical molecular diagnostics to differentiate between SA and PA in children." Perforated appendicitis has an incidence, according to one study[3], of at least 19% in children undergoing appendectomy.

The clinical study asked, "What blood-based mechanistic changes distinguish pediatric patients with perforated appendicitis (PA) from those with simple appendicitis on presentation to the emergency department?"

The study found that the "diagnostic study of 71 patients with pediatric appendicitis using systems immunology methods revealed a mechanistic understanding of severe disease, indicating immune dysregulation similar to that observed in sepsis. A blood-based gene expression signature of PA was also derived, providing a potential diagnostic for pediatric PA. Further work[4] indicated that the Sepset^{ER} gene signature was similarly diagnostic and, in fact, overlapped with the 4-gene signature."

The study concluded that early diagnostics and management strategies for pediatric PA should be informed by underlying immune dysregulation and similarities to sepsis. Given that Asep is in advanced pre-clinical development of their sepsis gene expression in vitro diagnostic test, Sepset^{ER}, it is likely that this test may assist with diagnoses of the most severe forms of childhood sepsis in the future.

Dr. Robert E. W. Hancock, Asep Medical's Founder, Chairman and CEO, commented, "This study took place in 2017 in Calgary, and we performed the final data analysis in August 2023. Using the gene expression signatures we developed at UBC, and now under patent and licenced to Asep Medical's subsidiary Sepset Biosciences, we were able to leverage this data to show the value of the Sepset^{ER} technology in identifying perforated appendicitis. Based on the new potential benefits of this ER technology, we look forward to improving outcomes for children presenting with abdominal pain in the ER."

ABOUT ASEP MEDICAL HOLDINGS INC.

Asep Medical Holdings Inc. (www.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 antibacterial peptide medical device coating technology).

Sepset Biosciences Inc. (www.sepset.ca) is in the final stages of preparation for clinical studies and commercialization of an in vitro diagnostic test that involves a patient gene expression signature that helps assess the development of severe sepsis, one of the significant diseases leading to antibiotic failure since antibiotics are the primary initial 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 SepsetER test is a blood-based gene expression assay that is straightforward to implement, and results are obtained 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, 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 physicians to make critical early decisions regarding appropriate therapies and thus reduce overall morbidity and mortality due to sepsis.

ABT Innovations Inc.'s (www.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 with promising data for the first three indications.

SafeCoat Medical Inc.'s (www.safecoatmedical.com) technology encompasses anti-fouling 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.

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 market authorization 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

1. Dhillon BK, S Kortbeek, A Baghela, M Brindle, D-A Martin, CN Jenne, HJ Vogel, AHY Lee, GC Thompson, and REW Hancock. 2024. Gene expression profiling in pediatric appendicitis. JAMA Pediatrics, online doi:10.1001/jamapediatrics.2023.6721
2. Pacilli M, Kamaleswaran R. New genetic biomarkers to diagnose pediatric appendicitis. JAMA Pediatr. Published online February 19, 2024. doi:10.1001/jamapediatrics.2023.6731
3. Körner H, K Söndenaa, JA Söreide, E Andersen, A Nysted, TH Lende, and KH Kjellevold. 1997. Incidence of acute nonperforated and perforated appendicitis: age-specific and sex-specific analysis. World Journal of Surgery Mar-Apr;21(3):313-7. doi:10.1007/s002689900235
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