## ASEP Medical Holdings Inc. Announces Public Listing on CSE to Drive Fight Against Antibiotic Failure

VANCOUVER, BC, Dec. 16, 2021 /CNW/ - ASEP MEDICAL HOLDINGS INC., ("**ASEP**" or the "**Company**") announces the public listing for trading of its common shares on the Canadian Securities Exchange (CSE: ASEP.CN).

ASEP (<u>www.asepmedical.com</u>) is dedicated to addressing antibiotic failure by developing novel solutions to large unmet medical needs. It represents the consolidation of two existing private companies, each of which ASEP own's a controlling interest, that are in advanced development of both proprietary diagnostic tools, enabling the early and timely identification of severe sepsis and broad-spectrum therapeutic agents to address multidrug resistant biofilm infections.

There is a major worldwide problem with antibiotic resistance that has led the World Health Organization to term it a "fundamental threat" since it leads to higher medical costs, prolonged hospital stays, and increased mortality<sup>1</sup>. Antibiotic resistance is on the rise and will increasingly lead to tremendous issues in treating patients<sup>1,2</sup>. However, there is an even larger problem that has already made infections one of the major causes of death and disability, the issue of antibiotic failure<sup>3</sup>. Thus, there are many medical situations in which antibiotics fail, not always because of genetic alterations of bacteria leading to resistance, but due to the circumstances in the patient that make the infection difficult or impossible to treat<sup>3,4</sup>.

For example, sepsis occurred in 49 million individuals globally in 2017<sup>5</sup>. For this syndrome antibiotics are the front-line treatment but in fact failed in 23% of patients leading to 11 million deaths, 19.7% of all deaths in 2017. Since then, the situation has worsened as sepsis is the cause of death in most patients who die from Covid-19<sup>6</sup>. ASEP proposes to address this with a novel diagnostic that is able to sense the dysfunctional immune response underlying the most severe form of sepsis, at the time that patients first enter the emergency room of a hospital. This will allow physicians to make timely decisions about the initiation of intensive life-saving therapy, as well as identify patients who are not at risk, thus sparing expensive treatments and reducing antibiotic usage that drives resistance.

One of the most extreme threats where antibiotics often fail is biofilm infections since they represent, according to the U.S. Food & Drug Administration ("**FDA**"), 65% of all infections and, due to the way they grow in the body are highly resistant to all antibiotics<sup>7,8</sup>. Biofilms are communities of bacteria encased in a protective matrix and can grow on any body surface or medical device. Staggeringly there is not a single FDA approved treatment for biofilm infections. ASEP scientists have demonstrated that their proprietary ABT peptides are able to preferentially attack biofilms formed from all medically important bacteria, work well in animal and human tissue models, and enhance the action of conventional antibiotics<sup>9</sup>. These peptides are also able to suppress inflammation that causes many of the medical issues due to chronic biofilm infections. Some examples of biofilm diseases include medical device infections, chronic infections, and many lung, bladder, wound, dental, skin, ear, nose, throat, sinusitis, and orthopedic infections, etc.

Dr. Rudy Mazzocchi, Chief Executive Officer of ASEP said "ASEP has developed groundbreaking approaches to dealing with antibiotic failure, with a rare combination of diagnostic and therapeutic technologies. We anticipate that ASEP will be able to address major medical markets that are not satisfied with the armament of antibiotics."

Dr. Robert E.W. Hancock, Co-Founder, Director and Chief Operating Officer of ASEP said, "We are pleased to address this important issue of antibiotic failure that has been overlooked by many. We

look forward to advancing these therapies into the clinic where they can really make a difference. The data generated to date is certainly very exciting."

## **ASEP's Business Approach**

Clinical testing of the sepsis diagnostic is underway, with the intention of filing for regulatory approval within the next 6-9 months. In the therapeutic area, it is proposed within the next year to move our lead product into formal pre-clinical studies preparatory to an Investigational New Drug (IND) application to enable fast-track clinical trials in man.

In addition to the Company's recent equity financing, funding to pursue its research agenda has been obtained through non-dilutive sources (e.g., through research and development grants and partnerships with other companies and entities). In the therapeutic area, ASEP is pursuing its broad array of molecules by developing them as new treatments either alone or through contractual arrangements with other companies. For more information, please visit: <u>www.asepmedical.com</u>.

## About ASEP Medical Holdings Inc.

ASEP Medical Holdings Inc. owns a controlling interest in Sepset Biosciences Inc. (<u>www.sepset.ca</u>) and ABT Innovations Inc. (<u>www.abtinnovations.ca</u>).

Sepset Bioscience Inc.'s SepsetER diagnostic technology involves a patient gene expression signature that predicts severe sepsis, one of the major diseases leading to antibiotic failure since antibiotics are the major treatment for sepsis but despite this Sepsis is responsible for nearly 20% of all deaths on the planet. The SepsetER test is identified in the blood and assessable by nucleic acid amplification technologies. This proprietary diagnostic technology differs from current diagnostic tests in enabling diagnosis of severe sepsis within 1-2 hours of first clinical presentation (i.e., in the emergency room), while other diagnostics only provide diagnosis after 24-48 hours. ASEP believes this will enable critical early decisions to be made by physicians regarding appropriate therapies and reduces mortality and morbidity.

ABT Innovations Inc.'s peptide technology covers a broad range of therapeutic applications including bacterial biofilm infections (medical device infections, chronic infections, lung, bladder, wound, dental, skin, ear-nose and throat, sinusitis, orthopedic, etc.), representing two thirds of all infections, anti-inflammatories, anti-infective immune-modulators and vaccine adjuvants.

#### **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, including but not limited to the completion of successful clinical testing of our Sepsis diagnostic test and its intended filing for regulatory approval; and the undertaking of pre-clinical studies on our lead therapeutic, with an expectation that this will lead to fast track clinical trials. Various assumptions were used in drawing the 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 those risk factors identified in the ASEP Medical's prospectus dated November 9, 2021) available for review under the ASEP Medical's profile at <u>www.sedar.com</u> and uncertainties and other factors that could cause actual events or results to differ materially from those projected in the forwardlooking statements. ASEP Medical 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.

# The CSE (operated by CNSX Markets Inc.) has neither approved nor disapproved of the contents of this press release.

#### REFERENCES:

- 1. O'Neill, J. 2016. Tackling drug-resistant infections globally: Final report and recommendations.
- https://amr-review.org/sites/default/files/160525\_Final%20paper\_with%20cover.pdf
- World Health Organization. 2019. Monitoring and evaluation of the global action plan on antimicrobial resistance.
- https://www.who.int/publications/i/item/monitoring-and-evaluation-of-the-global-action-plan-on-antimicrobial-resistance 3. Hancock, REW. 2020. The critical need for alternative approaches to address antibiotic treatment failure.
- hallcook, receive 2020. The critical need for alternative approaches to address antibiotic treatment railure. https://revive.gardp.org/the-critical-need-for-alternative-approaches-to-address-antibiotic-treatment-failure/
- Tillotson, G., et al. 2020. Antibiotic treatment failure and associated outcomes among adult patients with community-acquired pneumonia in the outpatient setting: A real-world US insurance claims database study. Open Forum Infectious Diseases, 7(3): ofaa065. <u>https://doi.org/10.1093/ofid/ofaa065</u>
- 5. Rudd, K.E., et al. 2020. Global, regional, and national sepsis incidence and mortality, 1990–2017: analysis for the Global Burden of Disease Study. Lancet. **395**(10219):200–11.
- Prescott, H.C., and T.D. Girard TD. 2020. Recovery from severe COVID-19: Leveraging the lessons of survival from sepsis. Journal of the American Medical Association 324.8:739–740. doi:10.1001/jama.2020.14103
- Høiby, N, et al. 2015. ESCMD\* guideline for the diagnosis and treatment of biofilminfections 2014. Clinical Mcrobiology and Infection, 21, (S1):S1-S25. https://doi.org/10.1016/j.cmi.2014.10.024.
- 8. Hancock, REW., M Alford, and EF. Haney. 2021. Antibiofilm activity of host defence peptides: Complexity provides opportunities. Nature Microbiol. Rev. 19:786–797.
- Wu, B.C., E.F. Haney, N. Akhoundsadegh, D. Retzer, M.J. Trimble, A.E. Adriaans, P.H. Nibbering and R.E.W. Hancock. 2021. Human organoid biofilm model for assessing antibiofilm activity of novel agents. NPJ Biofilms and Mcrobiomes <u>7</u>:8.

SOURCE ASEP Medical Holdings Inc.

View original content: <u>http://www.newswire.ca/en/releases/archive/December2021/16/c6048.html</u>

#### %SEDAR: 00053132E

**For further information:** Rudy Mazzocchi, ASEP Medical Holdings Inc., Email: rudy@asepmedical.com, Ph: +1.321.229.2014

CO: ASEP Medical Holdings Inc.

CNW 08:30e 16-DEC-21