

**December 3, 2018**

**FOR IMMEDIATE RELEASE**

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## **Wayne State University to lead U.S. clinical trials**

*Diagnostic to detect human sepsis in advance of clinical symptoms*

Calgary, Alberta – CNA Diagnostics Inc. today announced the signing of an agreement with Wayne State University to lead the U.S. clinical trials in support of FDA approval for its human sepsis diagnostic test, known as CNA Rapid Sepsis Dx. In proof-of-concept studies, CNA Rapid Sepsis Dx has proven capable of detecting bacterial and fungal human sepsis in advance of clinical symptoms, using blood serum and processed on industry standard RT-PCR equipment for turn-around of results in approximately four hours on site at a hospital or medical clinic. Wayne State University will provide access to tissue samples from a broad demographic of patients and a range of high-risk groups, as well as lead the U.S. clinical trials demonstrating the efficacy of CNA Rapid Sepsis Dx. In coordination with the company's co-founder and Chief Science Officer Dr. Christoph Sensen, the team will be led by Dr. Robert Sherwin, F.A.C.E.P., F.A.A.E.M., the clinical research director for Sinai Grace Department of Emergency Medicine, who also serves as the Chief Science Officer of ResearchOne at Wayne State University in Detroit. Dr. Sherwin has extensive clinical research experience in the fields of sepsis, resuscitation, emergency medicine, shock, hyperbaric medicine and hemodynamic monitoring, including prior work on diagnostics for human sepsis.

“The CNA Diagnostics’ method fills a vital need currently unmet by any other available diagnostic technology. It provides the opportunity to identify developing infections or sepsis in any emergency department or hospital patient days before there is clinical evidence or complications become irreversible. In the shift from a fee for service to a value-based reimbursement model, this fast and precise measurement of biomarker changes at the patient level will be mandated and a virtual game-changer. The CNA Diagnostics’ platform, through its unique approach of measuring the host’s specific response to a pathogen, epitomizes this concept of precision medicine and will represent an indisputable value for hospitals and healthcare facilities.” Stated Dr. Robert Sherwin.

“We are pleased to begin working with Wayne State, its network of hospital partners, and Dr. Sherwin as we undertake FDA and EMA regulatory approvals in support of commercialization,” said David Gordon, CEO of CNA Diagnostics Inc.. “The nexus of the research clinic, diagnostic lab services and working hospital will be important for the stakeholders to really grasp how early detection of sepsis can help save lives.” Based on pre-submission comments from the FDA, the clinical trials design and results will be used as validation studies in support of FDA approval as a medical device. Sample collection is expected to begin in early 2019, followed by completion of the clinical trials and submission of results to the FDA by the end of the year.

### ***About CNA Diagnostics:***

**CNA Diagnostics Inc.** is a molecular diagnostics company focused on the development of diagnostic tests for the early detection of the presence of disease in humans and animals (mammals). Test development is focused on disease stages prior to the onset of observable clinical symptoms, which currently cannot be detected reliably with existing commercially available methods. The company commercializes its tests primarily by licensing its technology to strategic partners for manufacturing, sales, distribution and service to end users in regions around the world.

### ***About Wayne State University:***

**Wayne State University** is a public research university located in Detroit. Founded in 1868, WSU consists of 13 schools and colleges offering over more than 350 degree programs to more than 27,000 graduate and undergraduate students. Wayne State University is Michigan's third-largest university, one of the 100 largest universities in the United States, and ranked in the top 50 American public universities for research expenditures. The Wayne State University School of Medicine (SOM) trains the next generation of physicians. The school offers master's, Ph.D. and M.D./Ph.D. programs in 14 areas of basic science and public health to about 400 students annually. The school's research emphasizes neurosciences, pediatrics, obstetrics and gynecology, perinatology, cancer, cardiovascular disease including diabetes and obesity, and psychiatry and addiction research. As many as 500 researchers and staff work out of the Integrative Biosciences Center, a 207,000-square-foot facility that was opened in October 2015 at a cost of \$92 million.

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