For Immediate Release

New Inflammatix Study in *Nature Communications* Outlines Breakthrough in Diagnosing Acute Infections by Reading the Immune System

Novel Machine Learning Host-Response-Based Approach Forms the Basis of Company's Tests

Burlingame, Calif., March 4, 2020 --- Inflammatix, a pioneering molecular diagnostics company delivering precision medicine at the point of care, announced findings from a new study published today in *Nature Communications* that demonstrate its ability to identify patients with bacterial versus viral infections using a data-driven approach that measures the immune system response. The molecular classifier used in the study forms the basis of Inflammatix's HostDx rapid tests, which the company is developing to overcome traditional challenges of diagnosing acute infections and sepsis.

"When seeing a sick patient with a suspected infection in the emergency room, most physicians are forced to basically make an educated guess about whether the patient has a bacterial or viral infection, and then treat accordingly. Unfortunately, despite best efforts, this guessing game can have terrible outcomes for patients and for our health system," said Tim Sweeney, M.D., Ph.D., cofounder and chief executive officer of Inflammatix.

"For 20 years, researchers have been looking for a way to use transcriptomics – the study of the body's gene expression – to classify patients with acute infections. To date, others' attempts to apply machine learning to this problem have not held up when applied to diverse patient populations. Our new study is the first time that a locked, multi-gene signature has been validated in a blinded, independent clinical cohort. It represents a major technical breakthrough in translating our tests to the clinic."

For the new publication, Inflammatix and Stanford University scientists applied advanced machine learning to develop a 29-gene classifier ("BVN-1") that can identify bacterial, viral or no infections across 1,069 blood samples from 18 prior studies of patients diagnosed with acute infections. The patients represented a wide range of geographic regions, clinical care setting and disease contexts.

The researchers then tested the locked classifier – i.e., without modification or retraining – on an independent cohort of 109 patients from Stanford University's intensive care unit who underwent evaluation for acute infection and sepsis. They found that the test was highly accurate in diagnosing infections, especially among patients tested within 36 hours of hospital admission – a critical time for determining treatment. Among this subset, the test demonstrated an AUROC of 0.92 (95% CI; 0.83-0.99) for identifying patients with bacterial infections and 0.91 (95% CI; 0.82-0.98) for viral infections.

The molecular classifier also demonstrated higher accuracy than standard biomarkers -- procalcitonin (PCT) and C-reactive protein (CRP) – that have been associated with acute infections and sepsis. Among the subset of patients with PCT and CRP results in the Stanford ICU cohort, the Inflammatix test had an AUROC of 0.87 (95% CI; 0.8-0.94) for bacterial infections, compared to 0.83 (95% CI; 0.75-0.92) for PCT and 0.70 (95% CI; 0.6-.081) for CRP. Neither PCT nor CRP could positively identify viral infections.

"To wit, 100 percent of the patients in this cohort were on antibiotics, but many did not have an underlying bacterial infection. Improved diagnostics would benefit patients and have a major impact on the healthcare system," said Dr. Sweeney.

"Furthermore, our machine learning team has demonstrated the power of our computational platform in a highly heterogeneous and difficult field. We look forward to bringing the same computational tools to bear across multiple other infectious and inflammatory diseases."

Antibiotic resistance and sepsis lead to more than 700,000[1] and 5 million[2] respective deaths worldwide each year. Inflammatix's HostDx Sepsis and HostDx Fever tests use proprietary machine learning algorithms that incorporate the expression of multiple immune genes (host response) to identify the presence of bacterial or viral infections and to determine if a patient has or is likely to develop sepsis. Inflammatix's simple-to-use, sample-to-answer HostDx system is designed to produce results at or near the point of care in 30 minutes or less. The company plans to advance its HostDx tests through commercial launch in Europe and submission to the United States Food and Drug Administration in 2021.

In January 2020, Inflammatix announced it had received $32 million in Series C financing. Prior to that, in November 2019, the company announced a cost-sharing contract with the Biomedical Advanced Research and Development Authority (BARDA), part of the U.S. Department of Health and Human Services' Office of the Assistant Secretary for Preparedness and Response, to further develop its HostDx tests. The agreement is worth up to $72 million based on achieving certain milestones.*

Citation

Mayhew, MB et al. A generalizable 29-mRNA neural-network classifier for acute bacterial and viral infections. Nature Communications, 2020. https://doi.org/10.1038/s41467-020-14975-w

About Inflammatix

Inflammatix is a molecular diagnostics company that is reimagining diagnostics by "reading" the patient's immune system to deliver rapid results that improve patient care and reduce major public health burdens. The company's initial focus is on acute infection and sepsis, where its HostDx™ tests combine proprietary biomarkers and advanced machine learning to help physicians quickly get the right treatments to the right patients. Each test will be developed to run on the company's sample-to-answer isothermal instrument platform in under 30 minutes, enabling the power of precision medicine at the point of care. The Burlingame, Calif.-based company funders include Khosla Ventures, Northpond Ventures, Think.Health Ventures, Grey Sky Venture Partners and the Stanford-StartX Fund. For more information, please visit www.inflammatix.com and follow the company on Twitter (@Inflammatix_Inc).

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[1] Interagency Coordination Group on Antimicrobial Resistance. No Time to Wait: Securing the Future from Drug-Resistant Infections; Report to the United Nations. April 2019.
[2] Rudd KE, et al. Global, regional, and national sepsis incidence and mortality, 1990–2017: analysis for the Global Burden of Disease Study. *Lancet* 2020; 395:200-211.