Bluejay Diagnostics, Inc. Announces Initiation of Multicenter Clinical Study Evaluating Symphony IL-6 in Sepsis Patients (SYMON Study)

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This Study performs unique rapid on-site measurements of interleukin-6 (IL-6) and positions Company to move forward with multiple initiatives.

ACTON, Mass., Dec. 27, 2023 (GLOBE NEWSWIRE) -- Bluejay Diagnostics, Inc. (NASDAQ: BJDX) ("Bluejay" or the "Company"), today announced the initiation of a multicenter clinical study to evaluate the Symphony IL-6 test in sepsis patients (the SYMON study). The Symphony System is designed to address the need for simple, reliable, rapid, near-patient testing by providing quantitative measurements of specific biomarkers to determine the need for additional patient care and monitoring. The Symphony System was shown in published clinical studies to deliver results directly from whole blood in approximately 20 minutes.

"Sepsis is a leading cause of hospitalization and mortality, with about 1.7 million people developing sepsis in the US alone," said Dr. Mark Feinberg, Bluejay's Chief Medical Advisor. "Any new tests or tools that can help better guide management of this critical population could be impactful to the medical field."

This study will use the Symphony IL-6 test to monitor IL-6 concentrations in patients who are diagnosed with sepsis or septic shock and are admitted or intended to be admitted to the ICU. The objective of this study is to establish IL-6 concentrations in these sepsis patients that best predict 28-day mortality. The study design incorporates feedback from the pre-submission meetings with the FDA held earlier this year. The details of this clinical study are listed on clinicaltrials.gov (NCT06181604) and will be updated as more clinical study sites are brought into the study.

"We are very excited to start these important studies," said Neil Dey, Bluejay's Chief Executive Officer. "In addition to being one step closer to commercialization, these studies will help to identify potential competitive advantages of the Symphony IL-6."

About Interleukin-6
Interleukin-6 (IL-6) is an established biomarker of immune system activation. It is elevated in sepsis, infection, inflammation, and cancer. IL-6 presents in blood circulation as an early "first responder" in conditions which cause inflammation, such as sepsis, and needs to be measured quickly and reliably.

About the Symphony™System*:*
Bluejay's Symphony System (the "Symphony System") is designed to address the need for simple, reliable, rapid, near-patient testing by providing quantitative measurements of specific biomarkers to determine the need for additional patient care and monitoring. The user-friendly Symphony System will not require any sample preparation or dedicated staff and was shown in published clinical studies to deliver results in approximately 20 minutes.

The Symphony IL-6 Test is a development stage product candidate for investigational use only. It is limited by United States law to investigational use.

About Bluejay Diagnostics:
Bluejay Diagnostics, Inc. is a medical diagnostics company focused on improving patient outcomes using its Symphony System, a cost-effective, rapid, near-patient testing system for triage and monitoring of disease progression. Bluejay's first product candidate, an IL-6 Test for sepsis, is designed to provide accurate, reliable results in approximately 20 minutes from 'sample-to-result' to help medical professionals make earlier and better triage/treatment decisions. More information is available at www.bluejaydx.com.

Forward-Looking Statements:
This press release contains statements that the Company believes are "forward-looking statements" within the meaning of the Private Litigation Reform Act. Forward-looking statements in this press release include, without limitation, the Company's expectations for conducting and completing clinical trials, including planned expansion to additional testing locations, the expected nature and timing of the Company's planned FDA submission, whether the Company's cash position will be sufficient to fund operations needed to achieve regulatory approval and initial commercialization of the Symphony IL-6 Test, and whether such regulatory approval will actually occur. Forward-looking statements may be identified by words such as "anticipates," "believes," "estimates," "expects," "intends," "may," "plans," "projects," "seeks," "should," "suggest", "will," and similar expressions. The Company has based these forward-looking statements on its current expectations and projections about future events, nevertheless, actual results or events could differ materially from the plans, intentions and expectations disclosed in, or implied by, the forward-looking statements the Company makes. These statements are only predictions and involve known and unknown risks, uncertainties, and other factors, including those discussed under item 1A. "Risk Factors" in our most recently filed Form 10-K filed with the Securities and Exchange Commission, as updated by the Company's subsequent Quarterly Reports on Form 10-Q. You should not place undue reliance on these forward-looking statements, as they are subject to risks and uncertainties, and actual results and performance in future periods may not occur or may be materially different from any future results or performance suggested by the forward-looking statements in this release. This press release speaks as of the date indicated above. The Company undertakes no obligation to update any forward-looking statements, whether as a result of new information, future events, or otherwise. The Company expressly disclaims any obligation to update or revise any forward-looking statements found herein to reflect any future changes in the Company's expectations of results or any future change in events.

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