Bluejay Diagnostics, Inc. Completes 90 Subjects in Multicenter Clinical Study Addressing Rapid IL-6 Test for COVID-19 Patients in Critical Care

January 13, 2022

This Study performs unique rapid on-site measurement using patient whole blood and positions Company to move forward with multiple initiatives

ACTON, Mass., Jan. 13, 2022 (GLOBE NEWSWIRE) -- Bluejay Diagnostics, Inc. (NASDAQ: BJDX) ("Bluejay", "the Company") a late-stage, pre-revenue diagnostics/medical device company focused on developing cost-effective, rapid, near-patient products for triage and monitoring of disease progression, today reported that it has completed 90 subjects in the prospective multicenter clinical study addressing rapid IL-6 test for COVID-19 patients with critical care. This study performs unique rapid on-site measurement using patient whole blood and positions the Company to move forward with multiple initiatives.

"This phase of our clinical studies is key not only for the progress towards commercialization, but to also demonstrate the competitive advantages that the Symphony System may bring to medical care," said Neil Dey, Bluejay's Chief Executive Officer. "With these studies, Bluejay is well positioned to move forward with several initiatives that will highlight the importance of IL-6 testing for the triage of patients with suspected Sepsis as well as other related conditions such as 'Cytokine Storm Syndrome' in COVID-19 patients."

Neil continued, "The early identification of this vulnerable patient population can help guide medical care to institute preventative treatments to improve patient prognosis. Furthermore, using IL-6 as an early warning indicator can assist healthcare systems to sequester critical resources in time to save lives."

Bluejay conducted its multicenter clinical study at two sites at the University of Texas Southwestern Medical Center's (William P. Clements Hospital and Zale Lipsey Pavilion Hospital), and at Parkland Memorial Hospital, all located in Dallas, Texas. These studies mark the first of their type, in which IL-6 is quantified directly from the whole blood of COVID-19 (SARS-CoV-2 positive) patients in critical care. The results from this multicenter study are currently being prepared for submission for scientific peer review and publication in the Q3:22 timeframe.

The study objectives were several fold including: 1) validating the use of unprocessed whole blood for the measurement of IL-6 (compared with the multistep laboratory processing required in current IL-6 measurements); 2) comparison of the Symphony produced measurement values relative to other current standard laboratory tests; 3) generation of the clinical data to support moving the Symphony IL-6 testing into potential commercial use; and 4) producing the results needed to support further approvals through FDA processes.

Bluejay intends to file its Pre-Submission application with the FDA in January 2022 for the Symphony IL-6 Test and to initiate an expanded clinical testing program. The results from this clinical program will form the basis of the Company's planned 510(k) marketing application, intended to be submitted in Q3:22.

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

About the Symphony IL-6 Test Program
Bluejay's initial testing program is proceeding as planned to support preparation for a Pre-Submission filing with the FDA, planned by the end of January, 2022. The initial Symphony IL-6 testing program is currently comprised of three studies:

- Study 1: cut-off: NCT05060250: to establish a value that classifies IL-6 levels in whole blood as low or high risk for intubation and with mechanical ventilation
- Study 2: cut-off validation: NCT05048927: to validate the IL-6 cut-off value in whole blood established in Study 1 in a separate set of samples
- Study 3: ref range: NCT05048888: to establish the range of IL-6 values in healthy individuals

The studies are being conducted at two sites at the University of Texas Southwestern Medical Center (William P. Clements Hospital and Zale Lipsey Pavilion Hospital) and at Parkland Memorial Hospital, in Dallas, TX.

The initial studies are intended to establish a reference range and define and validate the cut-off value for the Symphony IL-6 Test using whole blood samples. Initial data from Study 1 and Study 2 will be used to support the Pre-Submission filing expected by the end of January 2022.

The Company plans to expand the Symphony IL-6 Test program in Q1:22. Expanded data from these studies and other analytical testing studies will be used to generate the clinical and analytical validation data to support a 510(K) premarketing submission with the FDA, expected to be submitted by the end of Q3:22.

About the Symphony^{TM} System:
Bluejay's Symphony System (the Symphony System) is intended to address the need for simple, reliable, rapid near-patient testing. The Symphony System is designed to provide quantitative measurements of specific biomarkers to determine the need for additional patient care and monitoring, when used in combination with other test and laboratory measurements. The system does not require any sample prep and was shown in published

clinical studies to deliver results in about 24 minutes.

This user-friendly system is expected to fit into ICU/near-patient settings without the need for dedicated staff to run a test. The system has been designed to measure test analytes using whole blood. Samples are collected and loaded into proprietary, test-specific cartridges.

The Symphony System is based on a well-accepted test method (ELISA, Enzyme-Linked Immunosorbent Assay) using advances in nanotechnology and new approaches to microfluidics. Bluejay has an exclusive license to the Symphony System from Toray Industries (Toray), a multinational company with more than 96 years of manufacturing experience, located in Japan. The product is manufactured by Toray and Sanyoseiko. Sanyoseiko is an FDA-registered manufacturer with more than 50 years of global experience in medical devices manufacturing, located in Japan.

The Symphony IL-6 Test ("Symphony IL-6 Test") is currently Bluejay's lead product candidate. The Company intends to make a Pre-Submission filing for the Symphony IL-6 Test in January, 2022.

The Symphony IL-6 Test is a development stage product candidate for investigational use only. It is not approved or cleared for use in humans by any regulatory agency.

About Bluejay Diagnostics:
Bluejay Diagnostics, Inc. is a late-stage, pre-revenue diagnostics/medical device company focused on improving patient outcomes through the Symphony System, a more cost-effective, rapid, near-patient product candidate for triage and monitoring of disease progression in hospital and long-term acute care (LTAC) settings. Bluejay's first product candidate, an IL-6 test for sepsis triage, is designed to provide accurate, reliable results in approximately 24 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. These statements include, but are not limited to, statements relating to the expected timeline for the Pre-Submission application with the FDA, planned clinical studies and the planned 510(k) marketing application submission. Forward-looking statements are usually identified by the use of words such as "anticipates," "believes," "estimates," "expects," "intends," "may," "plans," "projects," "seeks," "should," "suggest", "will," and variations of such words or similar expressions or their negatives (as well as other words and expressions referencing future events, conditions, or circumstances). 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 in the Company's filings with the Securities and Exchange Commission, including as set forth in the "Risk Factors" section of the Company's final prospectus, which was filed with the Securities and Exchange Commission on November 11, 2021, as updated by the Company's subsequent Quarterly Reports on Form 10-Q. You should not place undue reliance on these statements, as they are subject to risks and uncertainties, and actual results and performance in future periods 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 changes in the Company's expectations of results or any change in events.

Investor Contact:
Alexandra Schuman
LifeSci Advisors
alex@lifesciadvisors.com
t: 646-876-3647