Bluejay Diagnostics Announces Successful Completion of Enrollment in the SYMON-II Multicenter Clinical Validation Study

July 21, 2026

750 Patients Enrolled Ahead of Plan in Pivotal Study Evaluating Symphony™ IL-6 for Early Assessment of 28-Day Sepsis Mortality Risk

ACTON, Mass., July 21, 2026 (GLOBE NEWSWIRE) -- Bluejay Diagnostics, Inc. (NASDAQ: BJDX), a medical diagnostics company developing rapid, near-patient diagnostic technologies for critical care, today announced the successful completion of patient enrollment in its SYMON-II multicenter clinical validation study. The study achieved its targeted enrollment of 750 patients earlier than the Company had originally anticipated, representing an important operational milestone in the development of the Company's Symphony™ rapid diagnostic platform.

SYMON-II is a prospective, multicenter clinical validation study designed to evaluate the ability of Bluejay's Symphony™ IL-6 test to assist clinicians in the early assessment of 28-day all-cause mortality risk in patients with sepsis who were admitted or intended for admission to the intensive care unit (ICU). The study enrolled patients across leading U.S. healthcare institutions, and the Company expects that it will provide the clinical dataset needed to analyze whether clinical evidence supports future regulatory submissions and commercialization efforts.

Preliminary observations from the enrolled population indicate an approximately 17% 28-day mortality rate, providing a robust clinical dataset for evaluating the prognostic utility of IL-6 in patients presenting with sepsis. Bluejay believes this event rate represents a clinically meaningful population and underscores the importance of early identification of patients at elevated risk of deterioration.

Dr. Mark Feinberg, Chief Medical Advisor of Bluejay Diagnostics, commented:

"Sepsis remains one of the leading causes of hospital mortality worldwide, and timely identification of patients at greatest risk continues to be one of the most significant challenges in emergency and critical care medicine. The successful completion of SYMON-II's enrollment represents an important advancement in evaluating the clinical utility of IL-6 as an early prognostic biomarker. The study's large, well-characterized patient population and meaningful number of mortality events are expected to provide a robust foundation for assessing the prognostic performance of IL-6. If supported by the study results, rapid IL-6 testing could help clinicians identify high-risk patients earlier, improve risk stratification and triage decisions, and potentially enable more timely therapeutic interventions."

"Successfully completing enrollment ahead of schedule is an important operational achievement and reflects the dedication of our clinical investigators, study coordinators, and Bluejay's clinical and technical teams," said Neil Dey, President and Chief Executive Officer of Bluejay Diagnostics. "The enrollment of 750 patients provides one of the largest prospective datasets focused on the role of IL-6 in early sepsis mortality risk assessment. We believe this study represents an important step toward bringing clinicians a rapid, near-patient tool capable of supporting earlier and more informed clinical decision-making in one of medicine's most time-critical conditions."

The Company expects to complete data cleaning, statistical analysis, and clinical reporting over the coming months. Results from the study are anticipated to be a critical component of Bluejay's planned regulatory strategy for the Symphony™ IL-6 platform.

The Symphony™ platform is designed to provide rapid, quantitative biomarker results directly at or near the patient's bedside, supporting clinical decision-making in emergency departments, intensive care units, and other critical care settings. The platform is intended to integrate seamlessly into existing clinical workflows while enabling future expansion to additional biomarkers and AI-enabled clinical decision support capabilities.

Completion of SYMON-II enrollment represents another important milestone in Bluejay's broader strategy to advance Symphony™ toward regulatory submission and commercialization.

Note: The Company's Symphony™ rapid diagnostic platform is an investigational device and is limited by United States law to investigational use.

About the SYMON Clinical Study Program:

The SYMON Clinical Study Program includes SYMON-I (clinicaltrials.gov ID NCT06181604), SYMON-II (NCT06654895), and SYMON-III (NCT07425587). SYMON-I is a pilot study to determine IL-6 levels associated with various endpoints, including, but not limited to 28-day all-cause mortality and in-hospital mortality. The SYMON-II study is the pivotal study to validate the outcomes of the SYMON-I study, which the Company plans to use to support a 510(k) application to the FDA. The SYMON-III study is a pilot study to determine IL-6 levels associated with patients presenting with increasing severity of infection in the emergency department and risk of developing sepsis.

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 sepsis triage and monitoring of disease progression. Bluejay does not yet have regulatory clearance for the Symphony System, and we will need to receive regulatory authorization from the U.S. Food and Drug Administration before Symphony can be marketed as a diagnostic product in the United States. 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 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 market and other conditions and those discussed under item 1A. “Risk Factors” in the Company’s Annual Report on Form 10-K for the fiscal year ended December 31, 2025, and in Part II, Item 1A, “Risk Factors” in its Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2026. 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, except as required by law. 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, except as required by law.

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