Bluejay Diagnostics, Inc. Announces Completion of 624 Patient Enrollments in SYMON-II Pivotal Clinical Trial

April 7, 2026

ACTON, Mass., April 07, 2026 (GLOBE NEWSWIRE) -- Bluejay Diagnostics, Inc. (“Bluejay” or the “Company”), a medical diagnostics company focused on rapid, near-patient testing, today announced the successful enrollment of 624 patients in its ongoing SYMON-II Trial, a pivotal clinical study evaluating the Company’s Symphony™ platform for interleukin-6 (IL-6) testing in critical care settings to determine patient acuity for sepsis triage and monitoring.

The SYMON-II study has a target enrollment of 750 patients, and the Company expects to complete enrollment within the next 2 to 3 months, subject to site activity and patient flow.

Importantly, the study’s inclusion and exclusion criteria have not caused a significant number of patients to be excluded from enrollment.

“This milestone reflects the strong execution by our clinical team and the continued commitment of our investigators and clinical partners,” said Neil Dey, CEO of Bluejay Diagnostics. “Reaching 624 enrolled patients positions us well to complete enrollment in the near term, bringing us closer to delivering meaningful clinical insights that could improve outcomes in critical care. We are particularly encouraged by the fact that study’s inclusion and exclusion criteria have not caused a significant number of patients to be excluded from enrollment.”

The SYMON-II trial is designed to support the clinical validation of Bluejay’s Symphony™ IL-6 test, which aims to provide rapid, near-patient results to aid clinicians in assessing patient severity and guiding timely decision-making in acute care environments.

With enrollment nearing completion, Bluejay anticipates progressing toward the next phases of clinical validation and regulatory submission activities, consistent with its broader strategy to advance near-patient testing and real-time monitoring in critical care settings, where timely decision-making is essential.

About the Symphony IL-6 Test:

The Symphony™ Test platform is designed to determine patient acuity for triage and monitoring based on the measurement of a specific biomarker. The Symphony™ IL-6 Test to determine patient acuity for sepsis triage and monitoring (“Symphony™ IL-6 Test”) is currently Bluejay’s lead product candidate.

Note: Investigational device. 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. 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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