SYMON-I Study of Symphony IL-6 Suggests Prediction of Mortality in Sepsis Patients

June 26, 2024

Results from primary analysis of the SYMON-I pilot clinical study consistent with IL-6 as a predictor of patients who have a mortality event with 28 days after sepsis and septic shock diagnosis and are admitted to the intensive care unit (ICU).

ACTON, Mass., June 26, 2024 (GLOBE NEWSWIRE) -- Bluejay Diagnostics, Inc. (NASDAQ: BJDX), today announced results from the primary analysis of SYMON-I, a multicenter pilot clinical study investigating the role of interleukin-6 (IL-6) in patients diagnosed with sepsis and septic shock. This prospective study assessed the utility of IL-6 upon initial presentation to the intensive care unit (ICU).

The primary analysis of the SYMON-I study (registered clinical trial number NCT06181604) highlighted that IL-6 levels within 24 hours of sepsis or septic shock diagnosis and admission to the ICU may predict patient mortality out to 28 days. These findings will be validated in the SYMON-II pivotal study.

Furthermore, a secondary outcome of the SYMON-I study showed that IL-6 levels within 24 hours of sepsis or septic shock diagnosis and admission to the ICU is a predictor of patient mortality during their hospitalization. Other secondary outcomes showed that lactate and Sequential Organ Failure Assessment (SOFA), standard clinical tests used for sepsis and septic shock patients, were not predictors of patient mortality out to 28 days.

Mark Feinberg, M.D., the Chief Medical Advisor to Bluejay Diagnostics and an Associate Professor of Medicine at Harvard Medical School, Boston, commented, “These results are a testament to the dedication of our team and the collaboration across centers. Understanding the role of IL-6 as a prognostic biomarker for mortality and other important critical care endpoints, may ultimately inform how IL-6 can be incorporated into the management of patients with sepsis or septic shock, potentially saving thousands of lives annually.”

Future Directions: Bluejay Diagnostics is planning to initiate the SYMON-II pivotal clinical study in Q3 2024. If the results are positive, the Company intends to use SYMON-II as support in a 510(k) application to the FDA in 2025 for the following intended use: Symphony IL-6 is intended for use to determine the IL-6 concentration as an aid in assessing the cumulative 28-day risk of all-cause mortality in conjunction with other laboratory findings and clinical assessments for patients diagnosed with sepsis or septic shock in the ICU. The Company intends to present the SYMON-I and SYMON-II results at future national scientific meetings and publish in peer-reviewed publications. The Company’s ability to engage in and complete these activities will be contingent upon it raising additional capital to continue funding its operations and remain a going concern.

Neil Dey, Chief Executive Officer at Bluejay Diagnostics, commented, “The SYMON clinical study program marks an important step forward in the fight against sepsis, offering potential new avenues for identifying patients at high risk of sepsis-associated mortality and opportunities for improving patient survival rates. Further studies are expected to build on these findings and refine the understanding of IL-6 as a key biomarker in managing sepsis effectively.”

About the Symphony System:

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.

About the SYMON Clinical Study Program:

The SYMON Clinical Study Program include SYMON-I and SYMON-II. 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.

About Bluejay Diagnostics: Bluejay Diagnostics, Inc. is committed to advancing healthcare by developing accessible, affordable, rapid and direct biomarker testing, in whole blood, near patient. Bluejay’s first product candidate, an IL-6 test for sepsis triage, 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. Based in Acton, Massachusetts, Bluejay aims to improve clinical outcomes through timely and precise diagnostic tests.

Symphony is a registered trademark of Bluejay Diagnostics, Inc.

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 nature and timing of the Company’s planned FDA submission and related plans for clinical study completion, 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, whether such regulatory approval will actually occur, and the continuation of the Company as a going concern. 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 Annual Report on Form 10-K for the fiscal year ended December 31, 2023, as updated by the Company’s Quarterly Report on Form 10-Q for the fiscal quarter ended March

31, 2024. 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.

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