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Zacks Small-Cap Research (NOTE)

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Bluejay Diagnostics, Inc. (BJDX: NASDAQ)

BJDX: SYMON Says: Start the Trial!

Research Note

Bluejay Diagnostics, Inc. (NASDAQ: BJDX) issued a press release on December 27th, 2023 informing stakeholders that the clinical study evaluating the Symphony diagnostic in sepsis patients has started. The trial has been designated SYMON: Multicenter **Sy**mphony IL-6 **Mon**itoring Sepsis ICU Study. The study has been listed on the clinicaltrials.gov website under the designator NCT06181604. The first subject is expected to be enrolled early in the new year and an interim readout could come as early as March.

As we discussed in our initiation, Bluejay initially launched a trial that sought to effectively triage COVID patients using IL-6 as a marker and determine their need for mechanical assisted ventilation. However, due to the dramatic decline in severe COVID patients in 2022, the trial design needed to be changed. The primary endpoint is now 28-day mortality and risk stratification of hospitalized sepsis patients. Cutoff values that will be used for the study are now being determined. The first subject is expected to be enrolled in January with an interim readout in March consisting of 100 patients. Our estimates call for the trial to be completed in 2024, followed shortly after by a regulatory submission using the 510(k) pathway. We further anticipate that a grant of marketing authorization will emerge in 2025, followed by commercialization. Bluejay has identified its market and plans to engage a small team of sales and marketing personnel in combination with partners and distributors to sell the devices and cartridges.

The inclusion criteria for the new trial requires that enrollees have a diagnosis of sepsis or septic shock as determined by a physician. Subjects must also be adults admitted or intended to be admitted to the ICU and provide a plasma sample within 12 hours of the earliest diagnosis of sepsis or septic shock. The plasma sample will be evaluated by the Symphony diagnostic.

Six centers are expected to be activated to enroll 140 subjects with the first, Beth Israel Deaconess Medical Center in Boston now cleared to start. There are several clinical trial agreements outstanding that should be signed shortly, which will provide additional sites. Beth Israel was the site where Thermo Fisher's device ran its procalcitonin trial in 2014. The approved device serves as Symphony's predicate device. The institutional knowledge at the site is expected to provide an edge for the development and approval of the anticipated 510(k) submission.

Sepsis is a leading cause of death in hospitals and physicians require accurate data on patient status before treatment. Existing testing approaches frequently require several time-consuming steps before a diagnostic can be run, consuming valuable time. Transportation, preparing the sample and waiting in queue for sufficient volume to justify a test requires a 24 – 48 hour wait to produce a result. However, physicians need answers immediately for critical care decisions. Due to the lack of rapid testing alternatives, we think Symphony could catalyze a substantial increase in IL-6 test volume, especially at the price point anticipated, to help guide physician decision-making in the emergent care setting.

Symphony System

Symphony is an automated diagnostic system, consisting of a fluorescence immuno-analyzer which uses a single-use diagnostic test cartridge with reagents integrated into the cartridge. The system uses a 'sample-to-result' format, which means that once a specimen is taken from the patient, it is placed in the cartridge and then the cartridge

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is placed inside the analyzer where the test is run without further technician intervention or use of additional reagent. This reduces test complexity and eliminates the need for highly trained and expensive laboratory technicians to run the tests. The platform is designed to enable simple, rapid, and cost-effective analysis from a single clinical sample, which will allow long-term acute care facilities (LTACs), hospitals and clinics that have not been able to afford more expensive or complex diagnostic testing platforms access to this tier of analysis. The device can provide affordable patient testing in time sensitive, life-threatening situations. The system also allows for a faster turnaround as it is used in-house. This contrasts with the traditional use of an off-site laboratory. On-site testing may also help support the decision-making process and help avoid potential penalties often imposed on LTACs by insurance companies and government programs for failure to monitor sepsis. The time to result for the system is less than 20 minutes.

Sepsis

Sepsis is a potentially life-threatening complication of an infection that occurs when the body's immune system overreacts and damages its own tissues and organs. It is a leading cause of death in hospitals worldwide, estimated to affect 1.7 million adults in the United States[1] and 47 to 50 million around the globe[2] each year. Over 20% do not survive or are at greater risk of rehospitalization and death. Further, sepsis survivors suffer from persistent impairments such as cognitive deterioration, brain dysfunction, cardiovascular events and an increased chance of hospital readmission in the weeks to months after discharge. It is caused by a number of factors including viral or bacterial infection, pneumonia and blood poisoning among others.

Sepsis falls into two categories: sepsis and septic shock. Sepsis is both the general term for all stages and a systemic response to an infection, characterized by inflammation and organ dysfunction. Symptoms can include fever, increased heart rate, rapid breathing and decreased blood pressure. Septic shock presents a more advanced response that includes organ dysfunction and low blood pressure that requires vasopressor medications to maintain blood pressure. Both sepsis and septic shock are medical emergencies and require immediate attention. Septic shock can be fatal if not treated immediately. Septic shock is a severe circulatory, cellular and metabolic dysregulation that has higher mortality than sepsis.

Summary

Bluejay has launched its pivotal trial for the Symphony IL-6 diagnostic evaluating mortality and stratifying the risk of hospitalized sepsis patients. We expect to see the first patient enrolled in January and an interim readout by March. The first site has been identified and others are expected to come online shortly.

[1] Centers for Disease Control and Prevention. What is Sepsis?
[2] Global Sepsis Alliance. Sepsis – A Global Health Crisis.

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