



## Bluejay Reports FDA Agrees to Consider its Plan to Pursue a De Novo Regulatory Pathway for the Symphony IL-6 Test

June 9, 2022

ACTON, Mass., June 09, 2022 (GLOBE NEWSWIRE) -- Bluejay Diagnostics, Inc. (NASDAQ: BJDY) ("Bluejay", "the Company"), a medical diagnostics company focused on developing cost-effective, rapid, near-patient products for triage and monitoring of disease progression, **today announced that the FDA has agreed to consider Bluejay's plan to pursue a De Novo submission for the Symphony IL-6 Test.**

In written feedback to the January 2022 submission of the FDA pre-submission briefing package, the FDA stated that Bluejay's Symphony IL-6 Test could be considered for the *De Novo* pathway.

Neil Dey, Chief Executive Officer, said "We are excited for the opportunity to pursue the *De Novo* regulatory pathway. This confirms our belief that the Bluejay Symphony IL-6 Test has the potential to provide an innovative solution to the market. Bluejay continues to advance the Symphony IL-6 Test towards the Company's anticipated marketing application with the FDA, expected by year-end 2022."

### **About the De Novo Classification**

If it is determined that there is not a legally marketed class I or class II device upon which to base a determination of substantial equivalence and a device is considered to be of low to moderate risk, the FDA may make a determination to classify the product candidate as a *De Novo* application, rather than the more conventional 510(k) marketing application. Information related to the *De Novo* classification can be found through the following link: [De Novo classification](#).

### **About the Symphony™ System:**

Bluejay's Symphony System (the Symphony System) is designed to address the need for simple, reliable, rapid near-patient testing by providing quantitative measurements of specific biomarkers to determine the need for additional patient care and monitoring. The user-friendly System does not require any sample prep or dedicated staff and was shown in published clinical studies to deliver results in approximately 20 minutes.

*The Symphony IL-6 Test is a development stage product candidate for investigational use only. It is limited by United States law to investigational use.*

### **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 product for triage and monitoring of disease progression. 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. More information is available at [www.bluejaydx.com](http://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. Forward-looking statements in this press release include, without limitation, the Company's ability to submit its marketing application with the FDA by the end of 2022 and whether the FDA determines to classify the Company's product candidate as a *De Novo* application. 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 under item 1A. "Risk Factors" in our most recently filed Form 10-K filed with the Securities and Exchange Commission ("SEC"), 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](mailto:alex@lifesciadvisors.com)  
t: 646-876-3647