



Quidel Receives FDA Clearance and CLIA Waiver for Its Point-of-Care Sofia® 2 Instrument for Use with Sofia Respiratory Syncytial Virus (RSV) Assay

June 28, 2017

SAN DIEGO--(BUSINESS WIRE)--Jun. 28, 2017-- **Quidel Corporation (NASDAQ: QDEL)**, a provider of rapid diagnostic testing solutions, cellular-based virology assays and molecular diagnostic systems, announced today it has received 510(k) clearance and Clinical Laboratory Improvements Amendments (CLIA) waiver from the United States Food and Drug Administration (FDA) for Quidel's Sofia RSV Fluorescent Immunoassay (FIA) to be used with the Sofia 2 Fluorescent Immunoassay Analyzer for the rapid detection of respiratory syncytial virus (RSV) infections in nasopharyngeal swab and nasopharyngeal aspirate/wash specimens taken directly from symptomatic pediatric patients.

Sofia 2 is Quidel's next-generation version of its best-selling Sofia instrumented system. Sofia 2 utilizes the original Sofia's fluorescent chemistry design while improving upon the graphical user interface and optics system to provide an accurate, automated and objective result in as few as 3 minutes. Sofia 2 also integrates wireless connectivity and its barcode scanner within a smaller footprint than the legacy Sofia instrument.

The next-generation Sofia system also comes connected to Virena®, Quidel's data management system, which provides aggregated, de-identified testing data in near real-time.

The Sofia RSV assay employs advanced lateral flow and immunofluorescence technologies to provide enhanced clinical sensitivity for RSV, one of the most serious respiratory diseases in children and seniors. These technologies help ensure a reliable, objective, rapid, and accurate diagnostic result. The Centers for Disease Control and Prevention (CDC) estimate that Respiratory Syncytial Virus, or RSV, leads to 2.1 million annual outpatient visits among children younger than 5 years old, and that 25% - 40% of young children infected with RSV for the first time will exhibit signs of pneumonia or bronchiolitis.^{1,2}

In addition to the several thousand hospitals, medical centers and smaller clinics in the United States, the receipt of CLIA waiver markedly expands the available market for the Sofia 2 test system.

"With the clearance of Sofia Influenza A+B and Sofia RSV on the new Sofia 2 instrument, we are now able to diagnose two of the most common respiratory diseases more quickly, more easily and at a lower cost; a perfect fit for the specific needs of the point-of-care space," said Douglas Bryant, president and chief executive officer of Quidel Corporation. "We see Sofia 2 building on the success of our original Sofia flagship product by expanding our instrument placements into the smaller, lower volume physician offices as well as the higher volume health systems, while also significantly growing our Virena wireless coverage throughout the country."

Sofia 2 received CLIA waiver for the Sofia Influenza A+B assay from the FDA in May, and is now available for sale in the U.S.

1. <https://www.cdc.gov/rsv/research/us-surveillance.html>

2. <https://www.cdc.gov/rsv/clinical/index.html>

About Quidel Corporation

Quidel Corporation serves to enhance the health and well-being of people around the globe through the development of diagnostic solutions that can lead to improved patient outcomes and provide economic benefits to the healthcare system. Marketed under the Sofia®, QuickVue®, D3® Direct Detection, Thyretain® and InflammDry® leading brand names, as well as under the new Solana®, AmpliVue® and Lyr® molecular diagnostic brands, Quidel's products aid in the detection and diagnosis of many critical diseases and conditions, including, among others, [influenza](#), [respiratory syncytial virus](#), Strep A, herpes, pregnancy, [thyroid disease](#) and [fecal occult blood](#). Quidel's research and development engine is also developing a continuum of diagnostic solutions from advanced lateral-flow and direct fluorescent antibody to molecular diagnostic tests to further improve the quality of healthcare in physicians' offices and hospital and reference laboratories. For more information about Quidel's comprehensive product portfolio, visit [quidel.com](#).

This press release contains forward-looking statements within the meaning of the federal securities laws that involve material risks, assumptions and uncertainties. Many possible events or factors could affect our future financial results and performance, such that our actual results and performance may differ materially from those that may be described or implied in the forward-looking statements. As such, no forward-looking statement can be guaranteed. Differences in actual results and performance may arise as a result of a number of factors including, without limitation, fluctuations in our operating results resulting from seasonality, the timing of the onset, length and severity of cold and flu seasons, government and media attention focused on influenza and the related potential impact on humans from novel influenza viruses, adverse changes in competitive conditions in domestic and international markets, changes in sales levels as it relates to the absorption of our fixed costs, lower than anticipated market penetration of our products, the reimbursement system currently in place and future changes to that system, changes in economic conditions in our domestic and international markets, the quantity of our product in our distributors' inventory or distribution channels, changes in the buying patterns of our distributors, and changes in the healthcare market and consolidation of our customer base; our development and protection of intellectual property; our development of new technologies, products and markets; our reliance on a limited number of key distributors; our reliance on sales of our influenza diagnostics tests; our ability to manage our growth strategy, including our ability to integrate companies or technologies we have acquired or may acquire; intellectual property risks, including but not limited to, infringement litigation; our debt service requirements; our inability to settle conversions of our Convertible Senior Notes in cash; the effect on our operating results from the trigger of the conditional conversion feature of our Convertible Senior Notes; the possibility that we may incur additional indebtedness; our need for additional funds to finance our operating needs; volatility and disruption in the global capital and credit markets; acceptance of our products among physicians and other healthcare providers; competition with other providers of diagnostic products; adverse actions or delays in new product reviews or related to currently-marketed products by the U.S. Food and Drug Administration (the "FDA"); changes in government policies; compliance with other government regulations, such as safe working conditions, manufacturing practices, environmental protection, fire hazard and disposal of hazardous substances; third-party reimbursement policies; our ability to

meet demand for our products; interruptions in our supply of raw materials; product defects; business risks not covered by insurance and exposure to other litigation claims; interruption to our computer systems; competition for and loss of management and key personnel; international risks, including but not limited to, compliance with product registration requirements, exposure to currency exchange fluctuations and foreign currency exchange risk sharing arrangements, longer payment cycles, lower selling prices and greater difficulty in collecting accounts receivable, reduced protection of intellectual property rights, political and economic instability, taxes, and diversion of lower priced international products into U.S. markets; dilution resulting from future sales of our equity; volatility in our stock price; provisions in our charter documents, Delaware law and our Convertible Senior Notes that might delay or impede stockholder actions with respect to business combinations or similar transactions; and our intention of not paying dividends. Forward-looking statements typically are identified by the use of terms such as "may," "will," "should," "might," "expect," "anticipate," "estimate," "plan," "intend," "goal," "project," "strategy," "future," and similar words, although some forward-looking statements are expressed differently. The risks described in reports and registration statements that we file with the Securities and Exchange Commission (the "SEC") from time to time, should be carefully considered. You are cautioned not to place undue reliance on these forward-looking statements, which reflect management's analysis only as of the date of this press release. Except as required by law, we undertake no obligation to publicly release the results of any revision or update of these forward-looking statements, whether as a result of new information, future events or otherwise.

View source version on businesswire.com: <http://www.businesswire.com/news/home/20170628006289/en/>

Source: Quidel Corporation

Quidel Contact:

Quidel Corporation

Randy Steward

Chief Financial Officer

(858) 552-7931

or

Media and Investors Contact:

Quidel Corporation

Ruben Argueta

(858) 646-8023

rargueta@quidel.com