Quidel Receives PMDA Approval for Its Point-of-Care Sofia® Influenza A+B Assay

May 24, 2017

SAN DIEGO--(BUSINESS WIRE)--May 24, 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 approval from Japan's Pharmaceuticals and Medical Devices Agency (PMDA) for Quidel's Sofia® Influenza A+B Fluorescent Immunoassay (FIA) to be used with the Sofia® Fluorescent Immunoassay Analyzer.

Sofia is the brand name for Quidel's instrumented immunoassay system. The easy-to-use Sofia Analyzer and Sofia Influenza A+B FIA combine unique software and fluorescent chemistry to yield an automatic, objective result that is readily available on the instrument's screen, in a hard-copy printout, and in a transmissible electronic form that can network via an LIS system to hospital and medical center databases.

The Sofia FIA employs advanced lateral flow and immunofluorescence technologies to provide enhanced clinical sensitivity for influenza A and B. The Sofia Analyzer provides for high-throughput batching methods, and other features designed to facilitate use in a variety of healthcare settings, including hospitals, medical centers, small clinics and doctors' offices. These features help ensure a reliable, objective, rapid, and accurate diagnostic result.

It is estimated that there were between 13 million to 16 million confirmed cases of Influenza in Japan every year between 2010 and 2014.[1]

"We are pleased to have received approval in Japan for our Sofia Influenza A+B assay, and are excited about the opportunity to expand Sofia's international footprint," said Douglas Bryant, president and chief executive officer of Quidel Corporation.

The Sofia® Fluorescent Immunoassay Analyzer, Sofia® Group A Strep Assay, and Sofia® RSV assay are also currently available for sale in Japan.

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1. http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0146520

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 InflammaDry® leading brand names, as well as under the new Solana®, AmpliVue® and Lyra® 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, our reliance on development of new technologies, fluctuations in our operating results resulting from the timing of the onset, length and severity of cold and flu seasons, seasonality, 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, the reimbursement system currently in place and future changes to that system, changes in economic conditions in our domestic and international markets, lower than anticipated market penetration of our products, 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 proprietary technology rights; 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 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; our need for additional funds to finance our capital or operating needs; the financial soundness of our customers and suppliers; 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 the indenture covering 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.

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