Quidel Receives FDA Clearance for Its AmpliVue(R) Hand-Held Molecular Diagnostic Test for Bordetella Pertussis

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SAN DIEGO, CA -- (Marketwired) -- 12/10/14 -- ***Quidel Corporation*** (NASDAQ: QDEL), a provider of rapid diagnostic testing solutions, cellular-based virology assays and molecular diagnostic systems, announced today that it has received clearance from the United States Food and Drug Administration (FDA) to market its AmpliVue Bordetella Assay for the detection of *Bordetella pertussis* nucleic acids isolated from nasopharyngeal swab specimens obtained from patients suspected of having a respiratory tract infection attributable to *Bordetella pertussis*.

Pertussis, or whooping cough, is a very contagious disease caused by the *Bordetella pertussis* bacteria, which attach to the cilia that line part of the upper respiratory tract where they cause inflammation.[1] Pertussis is spread from person to person through the inhalation of bacteria from an infected person's cough or sneeze. Symptoms, such as a runny nose, low-grade fever, or mild cough usually develop within 5-10 days after exposure, but sometimes appear as long as 3 weeks later. Although whooping cough can cause serious illness in children and adults, it is most dangerous for infants and babies. According to the Centers for Disease Control and Prevention (CDC), about half of infants younger than 1 year of age who get this disease require hospitalization.[2]

The incidence of pertussis has risen steadily over the last few years.[3] Factors that have likely contributed to the increased incidence of pertussis include a decline in vaccine use, waning vaccine-induced immunity in adolescent and adult populations, failure to receive booster shots later in life, and continued circulation of *B. pertussis* in our population.[4-5]

The AmpliVue Bordetella Assay is an easy-to-use, self-contained, handheld disposable molecular diagnostic test with superb clinical accuracy. The assay requires no upfront extraction of DNA and generates an accurate result in approximately 75 minutes. Like all FDA-cleared AmpliVue assays, the AmpliVue Bordetella Assay is CLIA-classified[6] as moderately complex and does not require the customer to invest in expensive thermocycling equipment. This benefit, plus less laboratory space requirements, can significantly lower a laboratory's cost when adopting new molecular testing methods.

"We are pleased to receive 510(k) clearance for our AmpliVue Bordetella Assay -- our fifth assay in the AmpliVue format. We've shown that we can harness our proprietary HDA technology to develop fast, accurate molecular diagnostic assays with a menu that matters to our customers," said Douglas Bryant, president and chief executive officer of Quidel Corporation. "Longer-term, we intend to leverage this technology for other molecular diagnostic applications that will be appealing to significant market segments and potentially to public health agencies worldwide."

Quidel's AmpliVue platform now enables laboratories of all sizes to perform highly sensitive and specific molecular tests. The AmpliVue Bordetella Assay expands to six (6) the list of detectable analytes for which this novel AmpliVue platform now has FDA clearance. These include Pertussis, C. difficile, Group A Strep, Group B Strep, HSV1 and HSV2.

1) http://www.cdc.gov/pertussis/about/causes-transmission.html
2) http://www.cdc.gov/pertussis/about/signs-symptoms.html
3) CDC. Provisional Pertussis Surveillance Report. 2013. http://www.cdc.gov/pertussis/downloads/pertussis-surveillance-report.pdf
4) Versteegh FGA, Schellekens JFP, Fleer A, Roord JJ. Pertussis: a concise historical review including diagnosis, incidence, clinical manifestations and the role of treatment and vaccination in management Rev Med Microbiol 2005; 16 (3): 79-89.
5) Atwell JE, Van Otterloo J, Zipprich J, Winter K, Harriman K, Salmon DA, Halsey NA, Omer SB. Nonmedical vaccine exemptions and pertussis in California, 2010. *Pediatrics* 2013; 132 (4): 624-30.
6) Clinical Laboratory Improvement Amendments of 1988 (CLIA). http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/index.html?redirect=/clia/

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 QuickVue®, D3® Direct Detection and Thyretain® leading brand names, as well as under the new Sofia®, AmpliVue® and Lyra ™ 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; the reimbursement system currently in place and future changes to that system; changes in economic conditions in our 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 quantity of our product in our distributors' inventory or distribution channels, changes in the buying patterns of our distributors and changes in the health care 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; limitations and covenants in our senior credit facility; that we may incur significant 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 US markets; volatility in our stock price; dilution resulting from future sales of our equity; and provisions in our charter documents and Delaware law that might delay stockholder actions with respect to business combinations or the election of directors. 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. We undertake no obligation to publicly release the results of any revision or update of these forward-looking statements, except as required by law.

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