Quidel Obtains Special 510(k) Clearance to Add Avian Influenza A (H7N9) Virus Analytical Reactivity Information to the Package Inserts for All Three of Its Rapid Diagnostic Tests for Influenza

July 15, 2013

SAN DIEGO, CA -- (Marketwired) -- 07/15/13 -- **Quidel Corporation** (**NASDAQ**: **QDEL**), a provider of rapid diagnostic testing solutions, cell-based virology assays and molecular diagnostic systems, received Special 510(k) clearance for an update to the Company's immunofluorescence-based Sofia® Influenza A+B FIA package insert to include analytical reactivity with an avian Influenza A (H7N9) strain, A/Anhui/1/2013, on July 5th, 2013. Clearances of additional Special 510(k)s for its QuickVue® Influenza A+B and QuickVue Influenza visually read tests were also granted (June 28th and July 5th, respectively). The package inserts for all three products are being updated accordingly.

The novel influenza A (H7N9) virus is an avian influenza virus that has been shown to infect people in close contact with infected birds. In China, according to the CDC, approximately 130 people are known to have been infected with this virus and as of May 30, thirty-six (36) have died.(1) This virus is an avian influenza virus and is not readily human-to-human transmissible, but it is a high risk virus with pandemic potential. So far, no human cases have been identified outside of China.

The Sofia Influenza A+B FIA and both QuickVue influenza tests have been shown to detect the cultured A/Anhui/1/2013 virus analytically. However, the performance characteristics of these devices with clinical specimens from people that are positive for the A/Anhui/1/2013-like influenza A (H7N9) infection have not been established. The Sofia Influenza A+B FIA and the two QuickVue influenza kits can detect influenza A viruses, including this novel avian virus, but they cannot differentiate influenza A subtypes -- i.e., they cannot specifically identify this novel avian A (H7N9) or other avian or human influenza A subtypes.

Douglas Bryant, Quidel's president and chief executive officer, commented, "The first human infection with the novel avian influenza A (H7N9) was reported in China on April 1, 2013 -- only three and one half months ago.