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A NOVEL VACCINE FOR H1N1 SWINE INFLUENZA

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Responding to what some health officials feared could be the leading edge of a global pandemic emerging from Mexico, American health officials declared a public health emergency on Sunday April 26, 2009 as 20 cases of swine flu were confirmed in the U.S., including eight in New York City. At this time Mexico was already in a state of alarm with virtually all schools, restaurants and businesses closed in Mexico City, resulting in an estimated economic loss of around U.S. $400M per day. On April 29, WHO raised the level of pandemic alert from **Phase 4 to Phase 5**, indicating that human-to-human spread of the virus had occurred in at least two countries in one WHO region. As of the end of May, over 15,000 cases of H1N1 had been confirmed in more than 53 countries, including 99 deaths, with 85 reported in Mexico alone. The case fatality rate in Mexico of H1N1 is estimated to be 1.5%, whereas in the U.S. it is only 0.1%. In addition, the virus seems to be behaving similarly to seasonal influenza, although the transmission rate is relatively high (est. 22-33% and similar to the usual transmission rate reported in children).

On May 19, WHO and the UN organized a meeting with influenza vaccine manufacturers to discuss the status of vaccine supply: Protein Sciences was the only invited vaccine manufacturer representing a "novel" manufacturing technology for influenza vaccines; other manufacturers are still relying on the growth of live influenza viruses, mostly using chicken eggs. Attendees were informed by WHO that if they were to ask manufacturers to switch production by June 30 to the new H1N1 strain, only 30% of the usual seasonal supply would be available since the manufacturers just started producing the B-component of the vaccine. By the end of July, approx 65% of the usual supply would be available. In addition, no seed virus was available to enable manufacturers to begin production at this time. Protein Sciences committed to transfer its manufacturing technology to other countries, which would enable rapid expansion and availability of its vaccine; for example, in Korea 50,000-L capacity exists that could supply millions of vaccine doses in a relatively short time. Furthermore, technology transfer would avoid the serious political impediments to exporting vaccine from manufacturing countries during a pandemic.

As discussed during last year's meeting, Protein Sciences is developing FluBlok, a recombinant HA vaccine produced in cell culture using the baculovirus vectors system. FluBlok provides an attractive alternative to the current egg-based influenza vaccine (TIV) manufacturing process and presents the possibility for safe and expeditious vaccine production. The high purity of the antigen enables administration at higher doses without a significant increase in side-effects in human subjects. The HA genes from the annual WHO recommended strains are cloned, expressed and purified using a general purification process. The insect cell - baculovirus production technology is a modern solution for rapid antigen production and this technology is particularly suitable for influenza where annual adjustment of the vaccine is required or to address health care emergencies as currently posed by the H1N1 swine flu influenza virus.

The speaker will discuss Protein Sciences' efforts to develop a rHA vaccine against the H1N1 A/California /04/2009 in record time. In addition, she will discuss plans and status of technology transfer to other countries/locations to ensure "true" pandemic preparedness.