PaxVax Presents Phase 1 Clinical Trial Data for Single-Dose Cholera Vaccine
Vaccine Candidate Found to be Well Tolerated and Immunogenic

Menlo Park, Calif., and Atlanta – November 14, 2012 – PaxVax Inc, which develops and commercializes innovative vaccines against infectious diseases in a socially responsible manner today announced results from a Phase 1 clinical trial of PaxVax’s single-dose oral cholera vaccine candidate at the 2012 American Society of Tropical Medicine and Hygiene (ASTMH) Annual Meeting in Atlanta. The results were presented by the company’s collaborator, Dr. Wilbur Chen of the University of Maryland, Baltimore. The vaccine candidate, PXVX0200 (also known as CVD 103-HgR), was found to be well tolerated and immunogenic.

Cholera is an acute intestinal infection caused by toxigenic Vibrio cholerae bacteria, generally acquired by ingesting contaminated water or food. According to the World Health Organization, the global disease burden is estimated to be 3–5 million cases and 100,000–130,000 deaths per year.

PaxVax’s vaccine candidate PXVX0200 is a single-dose, oral, live, attenuated cholera vaccine. This single-dose vaccine is the same attenuated vaccine strain, CVD 103-HgR, that was previously approved and marketed in six countries under the brand name “Orochol or Mutacol.” No vaccine for cholera is currently available in the United States and cholera vaccines available outside the U.S. require a two-dose regimen. A single-dose vaccine regimen would be more convenient for travelers, especially for those traveling on short notice, and can help improve compliance and reduce number of physician visits.

In the Phase 1 trial, a single oral dose of PXVX0200 was highly immunogenic; overall, seroconversion to vibriocidal antibody occurred in 89% of vaccinees by day 14. Onset of immune response induced by the vaccine was also rapid, with 80% of subjects demonstrating seroconversion by 10 days after administration. The vaccine was well tolerated; adverse events were infrequent, and generally mild and comparable to placebo. These data are in line with expectations based on historical clinical trial results with previous formulations of CVD 103-HgR.

“There is a need for a single-dose, oral cholera vaccine for travelers here in the United States and for use overseas when explosive epidemics break out in unsettled situations and delivering more than one dose is difficult to achieve,” said Robert Edelman, M.D., Associate Director for Clinical Research at the Center for Vaccine Development at the University of Maryland School of Medicine. “These preliminary data regarding the immunogenicity and tolerability of this promising vaccine candidate are encouraging.”

Marc Gurwith, M.D., Chief Medical Officer of PaxVax, commented: “We are very pleased with these data for our cholera vaccine candidate, and given the previous experience with Orochol we are very confident that our Phase 3 trials should be successful. We have begun scaling up manufacturing capabilities to be able to deliver millions of doses of vaccine upon regulatory clearance.”
The poster (LB-354 in session 128) is titled “Safety and immunogenicity of a single-dose live oral cholera vaccine strain CVD 103-HgR prepared from new master and working cell banks.”

About PaxVax
PaxVax is a privately held company established in 2007 to develop and commercialize innovative vaccines against infectious diseases. PaxVax has a clinical-stage product portfolio, including a cholera vaccine entering Phase 3 and a pandemic H5N1 influenza vaccine entering Phase 2. The company also has vaccines in development for HIV and anthrax under R&D contracts with NIH. The company’s proprietary adenoviral-based technology platform enables the rapid development of oral vaccines that can target any viral or bacterial protein antigen. The company's vaccine candidates are designed to be easier to manufacture, store, distribute, administer and deliver across the globe than conventional injectable vaccines while enhancing the desired immune response to the vaccine antigens. The company’s offices are headquartered in Menlo Park, Calif., and the R&D laboratories and licensed GMP production facility are based in San Diego, Calif.

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