Influenza vaccine demonstrates favourable immunogenicity and tolerability in clinical testing

January 29 2014

Singapore's Agency for Science, Technology and Research (A*STAR) and Switzerland's Cytos Biotechnology AG today announced that their influenza vaccine (gH1-Qbeta) met its primary endpoint for immunogenicity (seroconversion based on haemaglutination inhibition titres according to FDA criteria) in the Phase 1 clinical trial in healthy Asian volunteers. The induced immune response showed good cross-reactivity to recent drifted H1N1 strains. The H1N1 influenza vaccine candidate is based on Cytos' proprietary bacteriophage Qbeta virus-like particle (VLP) technology.

The clinical trial commenced in May 2013 and completed enrollment and treatment of all 84 healthy volunteers in August 2013. During this trial the volunteers received two injections of the vaccine, 21 days apart. A*STAR and Cytos are pleased to announce that the vaccine was safe and well tolerated No serious adverse events were reported during the trial. The induced immune responses were comparable to those of approved seasonal influenza vaccines.

A*STAR is developing the vaccine candidate under a collaborative research, development and commercialisation agreement entered into with Cytos in 2010, with the goal of providing the government of Singapore effective means of combatting influenza epidemics and pandemics. Under the agreement, Cytos retains the worldwide right to develop and commercialise the vaccine candidate globally, while

A*STAR subsidiaries have the right to develop and commercialise the vaccine for Singapore and other ASEAN countries and can earn royalties on worldwide net sales.

Christian Itin, PhD, Chairman and Chief Executive Officer of Cytos, commented, "We are encouraged to see seroconversion in patients treated with our bacterially derived recombinant flu vaccine and are evaluating next steps with our partner A*STAR. The results of this study further support the utility of our VLP vaccine platform for the treatment of infectious diseases."

Professor Alex Matter, Chief Executive Officer of D3 (Drug Discovery and Development) and A*STAR's Experimental Therapeutics Centre (ETC) said, "We are very pleased with the outcome of this trial. The favourable data demonstrates that the VLP-vaccine strategy is an effective one. We are now planning, in conjunction with Cytos, the next steps for this project."

Provided by Agency for Science, Technology and Research (A*STAR), Singapore

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