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GSK vaccine gets positive opinion from FDA committee

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GSK H5N1 vaccine gets positive opinion from US FDA advistory committee

Singapore: The US Food and Drug Administration's (FDA's) Vaccines and Related Biological Products Advisory Committee voted unanimously (14-0) that the safety and immunogenicity data of the H5N1 adjuvanted influenza vaccine candidate by GlaxoSmithKline supports its licensure for the active immunization for the prevention of disease in persons 18 years of age and older who are at increased risk of exposure to the influenza A virus H5N1 subtype contained in the vaccine.

"GSK has been collaborating with the US Department of Health and Human Services since 2006 to develop this H5N1 vaccine and we are pleased with the positive vote recommending its approval," said Mr Bruce Innis, vice president, GSK Global Vaccines Discovery and Development. "We now look forward to a final decision by the FDA later this year and to also continuing our collaboration with the US government on public health issues."

The committee provides the FDA with independent expert advice and non-binding recommendations for consideration, with the final decision on approval made by the FDA. According to agency regulations, the FDA is scheduled to conclude its

review for the vaccine in December 2012. If approved, the vaccine is to be used only according to official guidance from the US government.

The H5N1 influenza vaccine candidate, manufactured in QuÃ©bec, is a two-component vaccine consisting of a monovalent, inactivated, split A/H5N1 influenza virus antigen and the AS03 adjuvant system. In clinical trials, the most common solicited local reactions and general adverse events were injection site pain and swelling, muscle aches, headache, fatigue, joint pain, shivering and sweating.

The regulatory filing was previously announced in March 2012. The vaccine is currently approved in Europe under the brand name Pumarix.