Reviewer’s report

Title: A phase II, open-label, multicentre study to evaluate the immunogenicity and safety of an adjuvanted pandemic (H5N1) influenza vaccine in healthy Japanese adults

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Reviewer: Ning-shao Xia

Reviewer’s report:

I reviewed the article entitled “A phase II, open-label, multicentre study to evaluate the immunogenicity and safety of an adjuvanted pandemic (H5N1) influenza vaccine in healthy Japanese adults”. The data would be of interest for Japanese people and local government.

Major Compulsory Revisions:

1 Trials in other countries using the mentioned pandemic H5N1 influenza split-virion vaccine adjuvanted with AS03A has been reported, please compare the immunogenicity and persistency induced in Japanese population with the data in other population.

2 Please compare the immunogenicity and persistency of vaccine in seropositive population and seronegative population before vaccination.

3 Please present cumulative distribution curves for titers of HI antibodies for different age group and at different time point, to more clearly show the immunogenicity and persistency of the vaccine.

4 Although the titer was low, 5% of the participants were seropositive against all the three H5N1 viruses before vaccination, please analyze the possible reason for this high seropositivity.

Level of interest: An article whose findings are important to those with closely related research interests

Quality of written English: Acceptable

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:

I declare that I have no competing interests.