For Immediate Release

Daiichi Sankyo Company, Limited
Kitasato Daiichi Sankyo Vaccine Co., Ltd.

Announcement Regarding the Project of H5N1 Influenza Vaccines

TOKYO, Japan (March 6, 2014) - Daiichi Sankyo Company, Limited (hereafter, Daiichi Sankyo) announced in August 2011 that the group company Kitasato Daiichi Sankyo Vaccine Company, Limited (hereafter, Kitasato Daiichi Sankyo Vaccine) was selected for the Japanese Ministry of Health, Labour and Welfare's cell culture vaccine production facility capacity building grant, which is a part of the Ministry's second initiative for H5N1 vaccine development and production capacity building. Kitasato Daiichi Sankyo Vaccine has been preparing to build a system to supply vaccines by the end of March 2014.

After process validation of production at the actual plants, Kitasato Daiichi Sankyo Vaccine recognized in October 2013 that vaccine yields would decline during the purification process. The company considered countermeasures to improve the situation, but it was deemed impossible to achieve the original goal of creating a scheme by March 31, 2014 to supply vaccines for 40 million people in six months. Today, Kitasato Daiichi Sankyo Vaccine reported this fact and offered countermeasures to the Health Ministry’s Initiative to Build Development and Production Capacity for H5N1 Influenza Vaccines Assessment Committee.
Daiichi Sankyo and Kitasato Daiichi Sankyo Vaccine sincerely apologize for being unable to achieve the originally planned scheme in the timeframe allotted.

Daiichi Sankyo and Kitasato Daiichi Sankyo Vaccine will take the post-evaluation results of the Assessment Committee in earnest and make efforts throughout the company to faithfully carry out the mission.

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(Attachment) Summary of the report:

1. Vaccine overview (NDA currently filed for manufacture and marketing)

   1) Vaccine names

   ・Adsorbed cell culture-derived H5N1 influenza virus vaccine 30μg/mL intramuscular injection "Kitasato Daiichi Sankyo"

   ・Adsorbed cell culture-derived H5N1 influenza virus vaccine 60μg/mL intramuscular injection "Kitasato Daiichi Sankyo"

   2) Manufacturing

   Kitasato Daiichi Sankyo Vaccine

   3) NDA filing date

   June 19, 2013 (30μg/mL formulation), September 26, 2013 (60μg/mL formulation)

2. Current production capability

   In the original scheme using 30μg/mL formulation, we achieved to produce vaccine antigen yields which are necessary for providing vaccine to 40 million people in six months by using existing plants in culture processes of vaccine bulk production. However, it was emerged that in the two purifying processes; the zonal ultra-centrifugation process and final filtering process, the vaccine antigen yields would drop significantly. Currently, as a result, it is only possible to produce vaccine for approximately 20 million people at the final formulation.

   In addition, it was confirmed from the various test results that the above drop in yield does not affect the vaccine quality and the vaccines currently produce maintain high quality.

3. Main improvement plans to increase vaccine yields

   ① Improvement of zonal ultra-centrifugation process

   In this process, the vaccine antigen is purified by using an ultra-centrifugation extractor. However, due to the lack of adjustment of the process conditions at the actual plant, the expected yield could not be achieved. In future, the vaccine antigen yield will be increased by setting more suitable process conditions.

   ② Improvement of final filtering process

   The final filtering process is carried out in order to achieve required sterilization for vaccine injection. In this process, due to the clogging of vaccine on the filter, the expected yield could not be achieved. In future, the vaccine antigen yield will be increased by introducing suitable production facilities.