October 21, 2013

**Astellas and UMN announce Completion of Administration of Phase III Clinical Trials of Seasonal Flu Vaccine ASP7374**

Astellas Pharma Inc. (TSE: 4503; Headquaters: Tokyo; President & CEO: Yoshihiko Hatanaka) and UMN Pharma Inc. (TSE: 4585; Headquaters: Akita; CEO: Tatsuyoshi Hirano) today announced that the administration of the recombinant seasonal influenza HA vaccine ASP7374 (former code: UMN-0502) was successfully completed in new two currently ongoing Phase III clinical trials. Astellas Pharma has been pursuing drug development of this vaccine in cooperation with UMN Pharma.

One of these clinical studies aims to enroll 900 healthy volunteers aged from 20 to 64 years, and to evaluate the immunogenicity and safety of subcutaneously-administered ASP7374 compared with approved egg-derived trivalent inactivated vaccine to prove non-inferiority of ASP7374 to the egg-derived vaccine. Astellas Pharma is conducting this clinical study following the successfully-conducted clinical study among 1,060 elderly volunteers. Astellas Pharma and UMN Pharma announced the results of the clinical study in elderly volunteers on March 11, 2013 in the news release titled “Non-inferiority Observed in Phase III Clinical Trials of Seasonal Flu Vaccine ASP7374”.

Another clinical study aims to enroll 55 healthy volunteers aged 61 and over, and to evaluate the immunogenicity and safety of intramuscularly-administered ASP7374.

The recombinant seasonal influenza HA vaccine ASP7374 containing three different strains of antigens, has been produced by a cell-culture manufacturing method employing the Baculovirus Expression Vector System, a next-generation technology platform for manufacturing biopharmaceutical products. In the U.S., Protein Sciences Corporation obtained approval of this vaccine from the Food and Drug Administration in January 2013.


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