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Astellas and UMN Announce Summary Results in 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 summary results for two Phase III clinical trials of the recombinant seasonal influenza HA vaccine ASP7374 (former code: UMN-0502), that completed administration in October 2013.

One of these clinical trials enrolled 900 healthy volunteers aged from 20 to 64 years to compare the immunogenicity and safety of subcutaneously-administered ASP7374 with approved egg-derived trivalent inactivated vaccine and to prove non-inferiority of ASP7374 to the egg-derived vaccine.
This clinical trial showed non-inferiority of the recombinant seasonal influenza HA vaccine ASP7374 in comparison with the egg-based vaccine in terms of immunogenicity. No major safety problem was also observed in ASP7374 in this trial.

Astellas Pharma is conducting this clinical trial following the successfully-completed clinical trial among 1,060 elderly volunteers. Astellas Pharma and UMN Pharma announced the results of the clinical trial 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 trial enrolled 55 healthy volunteers aged 61 and over to evaluate the immunogenicity and safety of intramuscularly-administered ASP7374. This clinical trial showed favorable immunogenicity. No major safety problem was also observed in ASP7374 in this trial.

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 (BEVS), a next-generation technology platform for manufacturing biopharmaceutical products. Protein Sciences Corporation obtained approval of this vaccine from the U.S. Food and Drug Administration in January 2013.

Astellas Pharma and UMN Pharma believe that the results of these clinical trials showed favorable potential of the recombinant seasonal influenza HA vaccine ASP7374 produced by a cell-culture manufacturing method employing the BEVS.
Now, Astellas Pharma and UMN Pharma are preparing for the application for marketing approval of ASP7374 in Japan.

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