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

Astellas Pharma Inc. (TSE: 4503; Headquarters: Tokyo; President & CEO: Yoshihiko Hatanaka) and UMN Pharma Inc. (TSE: 4585; Headquarters: 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 the currently ongoing Phase III clinical trial. Astellas Pharma has been pursuing drug development of this vaccine in cooperation with UMN Pharma Inc..

This clinical study aims to enroll 1,020 elderly volunteers, and to evaluate the immunogenicity and safety of ASP7374 compared with approved egg-derived trivalent inactivated vaccine to prove non-inferiority of ASP7374 to the egg-derived vaccine.

The recombinant seasonal influenza HA vaccine ASP7374, which contains 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. In the U.S., Protein Sciences Corporation has completed clinical studies required for approval and submitted a Biologic License Application of this vaccine to the Food and Drug Administration.

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