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Non-inferiority Observed in Phase III Clinical Trial 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 summary results for Phase III clinical trial showed non-inferiority of the recombinant seasonal influenza HA vaccine ASP7374 (former code: UMN-0502) in comparison with the egg-derived vaccine in terms of immunogenicity. No major safety problem was also observed in ASP7374 in this study.

This clinical study enrolled 1,060 elderly volunteers to compare the immunogenicity and safety of ASP7374 with approved egg-derived trivalent inactivated vaccine and to prove non-inferiority of ASP7374 to the egg-derived vaccine.

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. Protein Sciences Corporation obtained approval of this vaccine from the U.S. Food and Drug Administration in January 2013.

For Media Inquiries
Corporate Communications, Astellas Pharma Inc. TEL: +81-3-3244-3201 FAX: +81-3-5201-7473
General Affairs Division, UMN Pharma Inc. TEL: +81-45-624-8341 E-mail:press@umnpharma.com