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Favorable Immunogenicity and Tolerability Observed in Phase I/II Clinical Trial for Seasonal Flu Vaccine ASP7374

Astellas Pharma Inc. (TSE:4503; Headquarters, Tokyo; President & CEO, Yoshihiko Hatanaka; "Astellas") and UMN Pharma Inc. (Headquarters, Akita; CEO, Shu-ichi Kanazashi; "UMN") today announced that the favorable immunogenicity and tolerability have been observed in Phase I/II clinical trial for the seasonal influenza HA vaccine ASP7374 (former code: UMN-0502). Astellas has been pursuing drug development of this vaccine in cooperation with UMN.

This clinical study enrolled 165 healthy adult volunteers, and aims to comparatively evaluate the immunogenicity and safety of two subcutaneous and one intramuscular doses of ASP7374 to determine the optimal clinical dose. As announced on September 15, 2011, the administration of ASP7374 had been successfully completed, and Astellas had been collecting the data.

Astellas and UMN are happy to announce that the favorable immunogenicity and tolerability has been observed, and no serious adverse events have been reported.

The seasonal influenza HA vaccine ASP7374, which contains three different strains of antigens, has been produced by the cell-culture manufacturing method employing the Baculovirus Expression Vector System (BEVS), a next-generation technology platform for manufacturing of biopharmaceutical products. In USA, Protein Sciences Corporation has completed all clinical studies required for approval, and submitted a Biologic License Application of this vaccine to the Food and Drug Administration (FDA).

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