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Immunogenicity and Favorable Tolerability Observed in Phase II Clinical Trial for H5N1 Influenza Vaccine ASP7373

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 immunogenicity and favorable tolerability have been observed in Phase II clinical trial for the H5N1 influenza HA vaccine ASP7373 (UMN's development code: UMN-0501). Astellas has been pursuing drug development of this vaccine in cooperation with UMN.

This clinical study enrolled 180 healthy adult volunteers, and aims to comparatively evaluate the immunogenicity and safety among the three doses of ASP7373 to determine the optimal clinical dose. ASP7373 was administered intramuscularly two times with three weeks interval. As announced on November 11, 2011, the administration of ASP7373 had been successfully completed, and Astellas had been evaluating the data.

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

The recombinant influenza HA vaccine (H5N1) ASP7373 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. UMN started the clinical development of ASP7373 in 2008 and has already completed three clinical studies in Japan.

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