



May 30, 2014

Astellas and UMN Announce Submission of Application for Marketing Approval of Recombinant Influenza HA Vaccine ASP7374 in Japan

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 Astellas has submitted an application for marketing approval of recombinant influenza HA vaccine ASP7374 to the Ministry of Health, Labour and Welfare in Japan for the prevention of influenza.

ASP7374 has been produced by a cell-culture manufacturing method employing the Baculovirus Expression Vector System (BEVS), a next-generation recombinant technology platform for manufacturing biopharmaceutical products. Protein Sciences Corporation obtained approval of this vaccine as a product name of Flublok[®] for the prevention of seasonal influenza from the U.S. Food and Drug Administration in January 2013.

This filing application is based mainly on results obtained from the Phase III clinical trials* and the Phase I/II trial** conducted in Japan.

With the submission of the application for marketing approval, Astellas Pharma pays a milestone payment to UMN Pharma.

Astellas Pharma and UMN Pharma expect to contribute to the improvement of public health through providing a new option of influenza prevention with ASP7374.

* Phase III clinical trials are comprised of three trials. Two of these clinical trials enrolled elderly volunteers and healthy volunteers aged 20 and over to compare the immunogenicity and safety of subcutaneously-administered ASP7374 with approved egg-derived inactivated vaccine using double-blind method and to prove non-inferiority of ASP7374 to the egg-derived vaccine. Another clinical trial enrolled healthy volunteers aged 61 and over to evaluate the immunogenicity and safety of intramuscularly-administered ASP7374.

** Phase I/II clinical trial enrolled healthy adult volunteers, and aims to comparatively evaluate the immunogenicity and safety of two subcutaneous and one intramuscular doses of ASP7374.

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