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Tokyo: North American pharmaceutical companies Protein Sciences Corporation and UMN Pharma Inc. have announced that Protein Sciences and UNIGEN Inc., a joint venture of UMN and IHI Corporation, entered into an agreement to source bulk Flublok influenza vaccine from Japan for the US market.

The drug substances will be manufactured at the Gifu (Japan) Plant of UNIGEN. UNIGEN manufactures Flublok for the Japan market in two 21,000 L bioreactors - ten times the scale the vaccine manufactured in the United States. With this added capacity, Protein Sciences could provide as many as 25 million additional doses of Flublok each year to the US flu vaccine supply.

The companies have been working together for months on the preparation of a submission to secure FDA licensure of the Gifu plant and have requested a Type C meeting to initiate the process. Two Flublok manufacturing facilities in the US operated by Protein Sciences are already licensed by the FDA. Flublok vaccine is FDA approved for all adults 18 years and older and studies are underway to secure licensure for younger age groups.

Dan Adams, Executive Chairman and Global Head of Business Development at Protein Sciences said, "The demand for Flublok is continuously increasing especially since we reported the results of our large field study that showed that Flublok provides significantly better protection in older adults than a traditional flu vaccine. Sourcing Flublok from the Gifu plant will allow us to provide enough vaccine to meet this growing need."

Tatsuyoshi Hirano, Chairman and CEO at UMN Pharma said, "We are pleased to partner with Protein Sciences to enter into the US flu vaccine market that is the biggest and two and a half times larger than Japanese market. We will expand the capacity of Gifu plant up to four 21,000 L biological reactors from two in order to meet the expected demands from Protein Sciences."

This agreement represents an expansion of the relationship between Protein Sciences and UMN Pharma. UMN Pharma holds a license from Protein Sciences for Flublok for the territories of Japan, China, Korea, Hong Kong, Taiwan and Singapore.

Astellas has the right to market Flublok in Japan.