



Protein Sciences, UMN Pharma and IHI Corporation Enter into an Agreement to Evaluate Sourcing Flublok[®] from Japan

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CT, USA and Japan—[Protein Sciences Corporation](#) (Meriden, CT and Pearl River, NY), UMN Pharma Inc. (Akita, Akita prefecture, Japan) and IHI Corporation (Koto-ku, Tokyo, Japan) announced today that they have entered into an agreement to assess the feasibility of sourcing the active ingredients of [Flublokinfluenza vaccine](#) from Japan. The drug substances would be manufactured at the Gifu (Japan) Plant of UNIGEN, a subsidiary of UMN Pharma in which IHI holds 50% of the common shares. UNIGEN manufactures Flublok for UMN Pharma at the 21,000L scale – ten times the scale the vaccine is manufactured in the United States. The Gifu plant has two 21,000L bioreactors and has the capacity to add six additional bioreactors.

UMN holds a license from Protein Sciences for Flublok for the territories of Japan, China, Korea, Hong Kong, Taiwan and Singapore. UMN is partnered with Astellas to market Flublok in Japan.

Dan Adams, Executive Chairman and Global Head of Business Development at Protein Sciences said, “We have established a solid manufacturing base for Flublok in the United States; however, we are constantly evaluating alternative sources of supply and the Gifu plant is potentially a very attractive source.”

Flublok is the world’s first recombinant protein-based vaccine for the prevention of seasonal influenza disease and is FDA approved for adults 18 and older. The vaccine is highly purified and does not contain any preservatives, egg proteins, gelatin or latex. In addition, Flublok contains three times more antigen than traditional flu vaccines*. Flublok is available this season in the U.S. and is fully reimbursed by Medicare and other insurances.

About Protein Sciences

Protein Sciences specializes in vaccine development and protein production. Our mission is our inspiration: to save lives and improve health through the creation of innovative vaccines and biopharmaceuticals.

Flublok, the world’s first recombinant protein-based vaccine for the prevention of seasonal influenza disease, was approved by FDA in January 2013. Flublok is the only flu vaccine made in a 100% egg-free system using modern cell culture technology, making it unnecessary to use an

infectious influenza virus or antibiotics in manufacturing. Flublok is highly purified and does not contain any preservatives (e.g., thimerosal, a mercury derivative), egg proteins, gelatin or latex. In addition, Flublok contains three times more antigen than traditional flu vaccines (3x45mcg hemagglutinin protein versus 3x15mcg hemagglutinin protein)*. Flublok is a perfect copy of the virus coat and is not subject to the egg-adapted mutations associated with low vaccine effectiveness (see [Skowronski et al. \(2014\) PLOS ONE 9\(3\), e92153](#)).

Healthcare professionals can order Flublok by contacting FFF Enterprises at 800-843-7477.

Learn more at www.proteinsciences.com and www.flublok.com.

About IHI Corporation

IHI Corporation (Koto-ku, Tokyo) was established in 1853. It is a heavy industries manufacturer undertaking design and manufacture related to shipbuilding, aerospace, turbines and various plants. In January 2010, UMN and IHI concluded a 'basic agreement on cooperation' for joint business, concerning the manufacture of new bio-pharmaceutical ingredients using BEVS technology, including pharmaceutical ingredients such as UMN-0502 developed by UMN Pharma. With this cooperation agreement, UMN Pharma and IHI established UNIGEN Inc. focusing on the production of pharmaceutical ingredients required for recombinant influenza HA vaccine in May 2010. Gifu Plant, a world-renowned bio-pharmaceutical drug production facility, was established in May 2013 and is jointly operated by UMN Pharma and IHI.

About UMN Pharma

UMN Pharma is a bio-venture established in 2004 and is headquartered at Akita, Akita prefecture in Japan. The company received a license from Protein Sciences for dealership and exclusive development and manufacture of the recombinant influenza HA vaccine in Japan in August 2006 and for other regions in Asia (China, Korea, Taiwan, Hong Kong and Singapore) in October 2010. In Japan, the company concluded a cooperation agreement for joint development and exclusive sales of the recombinant influenza HA vaccine with Astellas Pharma in September 2010. The companies have submitted an application for approval of manufacture and sale of the recombinant seasonal influenza HA vaccine UMN-0502 (Astellas Pharma development code: ASP7374) to the Ministry of Health, Labor and Welfare, based on its results and efficacy on May 30, 2014.

Flublok Safety Information

Flublok is approved for people 18 and older to prevent influenza disease. The most common side effect from Flublok is pain at the site of injection. Headache, fatigue or muscle ache may occur.

Tell the doctor if you have ever experienced Guillain-Barré syndrome (severe muscle weakness) or have had a severe allergic reaction to any component of Flublok vaccine.

Vaccination with Flublok may not protect all individuals. Clinical effectiveness in adults 50 and older is based on the immune response elicited by Flublok and not on demonstration of decreased influenza disease.

Please see the complete Package Insert available at www.flublok.com or call 203-686-0800 for more information.

*Flublok demonstrated a higher antibody response to the A strains during 2 clinical trials in adults ≥ 50 years old. The B strain antibody response was comparable to traditional trivalent vaccines.