



Protein Sciences and UNIGEN Reach Agreement to Source Flublok[®] Influenza Vaccine from Japan

Expanded capacity could supply up to 25 million doses to U.S. market

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USA and Japan — [Protein Sciences Corporation](#) (Meriden, CT and Pearl River, NY) and UMN Pharma Inc. (Akita, Akita prefecture, Japan) announced today that Protein Sciences and UNIGEN Inc., a joint venture of UMN and IHI Corporation (Koto-ku, Tokyo, Japan), entered into an agreement to source bulk [Flublok influenza vaccine](#) from Japan for the U.S. market. The drug substances will be manufactured at the Gifu (Japan) Plant of UNIGEN. UNIGEN manufactures Flublok for the Japan market in two 21,000L bioreactors – ten times the scale the vaccine is 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 U.S. 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 U.S. 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 U.S. 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.

About Protein Sciences and Flublok

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 wishing to order Flublok should contact one of the following distributors:

- FFF Enterprises: 800-843-7477 www.myfluvaccine.com
- Cardinal Health: 866-677-4844 <http://www.cardinal.com/us/en/SPD/Ordering>
- McKesson: 877-MCK-4FLU mms.mckesson.com
- Henry Schein: 1-800-772-4346 www.henryschein.com

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

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.

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