



## **FOR IMMEDIATE RELEASE**

### **Press Release**

### **Memorandum of Understandings for UMN Pharma's Cell Culture Based Influenza Vaccine Programs in Japan**

**Tokyo and Akita, Japan, August 17, 2010** - Astellas Pharma Inc. ("Astellas"; headquarters: Tokyo; President and CEO: Masafumi Nogimori) and UMN Pharma Inc. ("UMN Pharma"; headquarters: Akita, President & CEO: Shu-Ichi Kanazashi) announced today that the both companies entered into a memorandum of understandings ("MOU") for UMN-0501 and UMN-0502 (the "Licensed Programs"), which are cell culture based influenza vaccine programs developed by UMN Pharma, to co-develop and exclusively commercialize in Japan, on August 16, 2010. A definitive agreement is planned to be concluded in this September.

UMN-0501 is a cell culture based H5N1 avian influenza vaccine manufactured through BEVS (Baculovirus Expression Vector System), a next generation technology platform for manufacturing of biopharmaceutical products. UMN-0501 was granted orphan drug status in June 2008, and Phase I/II and Phase II clinical trials in Japan have been successfully completed with both immunogenicity and safety identified. Currently, it is under preparation for Phase III clinical trial in Japan. Also, Blood and Blood Products Division of Pharmaceutical and Food Safety Bureau of Ministry of Health, Labour and Welfare was accepting applications for the project for development and manufacturing of novel "pandemic" influenza vaccine in February 2010. UMN Pharma applied for the project and was adopted on July 6, 2010. UMN-0502 is a cell culture based seasonal influenza vaccine, containing three different antigens, with the same manufacturing methods as UMN-0501. Currently, it is under preparation for Phase I/II clinical trial in Japan.

Under the terms of the MOU, Astellas is granted co-development and exclusive commercialization rights for the Licensed Programs in Japan. Astellas will lead the further development and bear all the costs. UMN Pharma is responsible for manufacturing, will supply the final commercial products to Astellas, and Astellas will be selling the commercial products.

In accordance with the recently announced mid-term management plan toward FY2014, Astellas is committed to reinforce vaccine business in Japan, and entered into the MOU as a part of it. UMN Pharma will be able to establish a seamless value chain in research, development, manufacturing and distribution.

The both companies expect to launch UMN-0501 and UMN-0502 by the end of FY2014 and are pleased that this MOU will contribute to Japanese government's urgent countermeasures against novel "pandemic" influenza through providing novel influenza vaccine.

The impact from this deal on Astellas' financial forecast for the current fiscal year (from April 1, 2010 to March 31, 2011) is immaterial.

#### **About BEVS**

BEVS is a technology enabling to manufacture a recombinant protein in a large scale by integrating target gene information to baculovirus vector and transmitting the vector to insect cells. UMN Pharma manufactures the Licensed Programs, by the use of *expresSF+*<sup>®</sup> cells from *Spodoptera frugiperda*, which is established by Protein Sciences Corporation (US). Protein Sciences Corporation and

UMN Pharma entered into an exclusive licensing agreement for influenza vaccine programs utilizing BEVS in Japan in August, 2006.

Cell culture based vaccines have some advantage, including quickness, capability to manufacture vaccine identical to prevalent strain and manufacturing safety, over the egg culture based vaccines. BEVS is an established technology utilized for some launched products.

### **About UMN Pharma**

UMN Pharma was incorporated in 2004 as a company dedicated to developing innovative pharmaceutical drugs that will satisfy unmet medical needs. Through our extensive network of Japanese universities and companies, we scout highly promising earlier stage drug seeds with the potential to become medical products, and promote their efficient development. Our pipeline includes vaccines against influenza and a therapeutic agent for the treatment of muscular dystrophy.

Incorporated: April 20, 2004

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### **About Astellas**

Astellas Pharma Inc., located in Tokyo, Japan, is a pharmaceutical company dedicated to improving the health of people around the world through the provision of innovative and reliable pharmaceutical products. Astellas has approximately 15,000 employees worldwide. The organization is committed to becoming a global category leader by rapidly establishing a business model in urology, immunology & infectious diseases, neuroscience, DM complications & metabolic diseases and oncology. For more information on Astellas Pharma Inc., please visit Astellas' website at <http://www.astellas.com/en>.

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