



October 5, 2009

For Immediate Release

UMN Pharma, Inc.

**UMN Pharma Initiates Phase II Clinical Trial for Avian Influenza A (H5N1)
Vaccine Manufactured from Cell-Culture, UMN-0501.**

UMN Pharma Inc. (headquartered in Akita, President & CEO: Shu-Ichi Kanazashi) today announced initiation of phase II clinical trial with UMN-0501, UMN's avian influenza A (H5N1) vaccine manufactured by cell-culture. The purpose of this clinical study is to evaluate immunogenicity^{*1}, safety and optimal dose in 90 healthy young adults aged 20-40. This study is conducted at two medical institutions in Tokyo and Osaka. Study results will be obtained by next February.

UMN-0501 is a new avian influenza vaccine manufactured from cell-culture using recombinant protein^{*2} by means of genetic recombination technology. Traditional vaccine production methods utilizing embryonated chicken eggs require at least six months for manufacturing, whereas UMN-0501 can be produced in approximately eight weeks. Therefore, UMN-0501 is expected to enable large-scale production of vaccine in significantly less time than traditional methods. Prior to phase II clinical trial, phase I/II clinical trial were conducted in last year. Study results confirmed that UMN-0501 provided immunogenicity against a natural strain of avian influenza virus, which was not attenuated^{*3}. The tolerability of UMN-0501 was good with no serious or highly adverse side effects diagnosed by the principal investigator. Based on phase I/II results, UMN has initiated phase II clinical trial. UMN increases the quantity of antigen administered in order to improve immunogenicity. In line with the commencement of clinical trials, UMN will begin construction of a vaccine manufacturing facility in Akita City with the capacity to produce vaccine stockpiles for up to 10 million people per year.

Shu-Ichi Kanazashi, the President and Chief Executive Officer of UMN Pharma Inc., comments that "Amid concerns over the crisis of a highly-pathogenic avian influenza^{*4} H5N1 outbreak, we will faithfully advance UMN-0501 through clinical trials and construction of a vaccine manufacturing facility as quickly as possible so that we can provide a steady supply of UMN-0501 to the public."

Note)

- *1 Immunogenicity
Property that can elicit an immune response.
- *2 Recombinant protein
A protein produced by gene recombination technology. The proteins can be artificially produced by inserting desired genes into the cells of Escherichia coli, yeast, insects and animals. The recombination proteins of insulin, interferon and antibody medicine have already been approved as medicines.
- *3 Attenuation (attenuated)
To lower the pathogenicity of virus by genetic manipulation without damaging the viability of the virus. In the general manner of vaccine production, allowing the virus itself to grow, the virus is attenuated to avoid the death of embryonated chicken eggs and cells for transmitting the virus. Our method of vaccine production does not need the process of attenuation because it only produces antigen without allowing the virus to grow.
- *4 Highly-pathogenic avian influenza
influenza caused by viruses adapted to birds. Of the greatest concern is highly pathogenic avian influenza (HPAI). Influenza A virus subtype H5N1 is a subtype of the Influenza A virus which can cause illness in humans and many other animal species. Pandemic avian influenza occurs when the avian influenza virus emerges in people and mutates allowing sustained person-to-person transmission. It may cause serious illness and can easily sweep across the country or world in a very short amount of time, thereby potentially causing a pandemic outbreak.



About UMN Pharma Inc.

UMN Pharma Inc. 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 pancreatitis.

Incorporated: April 20, 2004

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