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For Immediate Release

UMN Pharma, Inc.

**UMN Pharma Confirms Immunogenicity and Safety of
Avian Influenza A (H5N1) Vaccine Manufactured from Cell-Culture,
UMN-0501 in Phase II Clinical Trial**

UMN Pharma Inc. (headquartered in Akita, President & CEO: Shu-Ichi Kanazashi) today announced Phase II clinical trial results for UMN-0501^{*1}, UMN Pharma's avian influenza A (H5N1) vaccine manufactured by cell-culture.

The purpose of this clinical trial was to evaluate immunogenicity^{*2}, safety and optimal dose in 90 healthy young adults aged 20-40. Two doses of 45µg, 90µg or 135µg of UMN-0501 were administered by intramuscular injection at 21-day interval.

Trial results confirmed that UMN-0501 provided dose-dependent immunogenicity against a wild-type strain of avian influenza A (H5N1) virus, which was not attenuated. 90µg and 135µg of UMN-0501 nearly met the criteria for assessment of vaccines [The note for guidance on harmonisation of requirements for influenza vaccines (CPMP/BWP/214/96) ^{*3}]. The main local adverse events were pain, erythema and pruritus. The main systemic adverse events were headache, myalgia and diarrhea. There is no serious adverse event and severe systemic adverse event during the study period. UMN-0501 was well tolerated up to 135µg.

UMN Pharma is planning Phase III clinical trial based on this Phase II trial results confirmed considerable immunogenicity and safety. In addition, UMN Pharma is planning to conduct clinical trials to determine the immunological memory, therefore, the subjects participated in this Phase II clinical trial will be received UMN-0501 manufactured from another strain of H5N1.

Shu-Ichi Kanazashi, the President and Chief Executive Officer of UMN Pharma Inc., comments that "We confirmed considerable immunogenicity and safety of recombinant hemagglutinin vaccine. Amid concerns over the crisis of a highly-pathogenic avian influenza^{*4} H5N1 outbreak, we will faithfully advance UMN-0501 through clinical trials and develop UMN-0501 to dispel the fears of the public."



Note)

*1 UMN-0501

UMN-0501 is a new avian influenza vaccine manufactured from cell-culture using 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 recombinant proteins of hepatitis B, human papillomavirus, insulin, interferon and antibody medicine have already been approved as medicines.) 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 wild-type 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.

*2 Immunogenicity

Property that can elicit an immune response.

*3 The note for guidance on harmonisation of requirements for influenza vaccines

The following serological assessment should be considered for each strain in adult subjects aged between 18 and 60, and at least one of the assessments should meet the indicated requirements:

- Number of seroconversions or significant increase in anti-hemagglutinin antibody titer >40%;
- Mean geometric increase >2.5;
- The proportion of subjects achieving an hemagglutinin inhibition titer $\geq 40\%$ or single radial hemolysis (SRH) titer $>25\text{mm}^2$ should be >70%.

*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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