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For Immediate Release

UMN Pharma, Inc.

UMN Pharma Confirms Immunogenicity and Safety of UMN-0501 Pandemic Influenza Vaccine in Phase I/II Clinical Trials

UMN Pharma Inc. (headquartered in Akita City, Akita Prefecture, President & CEO: Shuichi Kanazashi) today announced Phase I/II clinical trial results for UMN-0501, UMN's pandemic influenza vaccine.

UMN-0501 is a new pandemic influenza vaccine manufactured from cell culture using recombinant protein 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. UMN-0501 has been granted orphan drug designation by the Ministry of Health, Labour and Welfare.

Phase I/II clinical trials were launched in June of 2008 and were conducted in a total of 125 healthy adult patients. The trial design called for the administration of vaccine with and without aluminum hydroxide (Alum) to study participants separated into five treatment groups. Alum is sometimes included as an adjuvant in vaccines to improve the quantity of antigen^{*1} and the immunogenicity of the vaccine. The aim of this study was to assess safety, efficacy and appropriate dose in healthy adult males between the ages of 20-40. Study results confirmed that UMN-0501 provided immunogenicity in the group administered vaccine without alum against a natural strain of pandemic influenza virus, which was not attenuated^{*2}. The tolerability of UMN-0501 was good with no serious or highly adverse side effects diagnosed by the principal investigator. In addition, the occurrence of pain at the site of inoculation for the group treated with vaccine without Alum was very rare.

These results will be released at 5th WHO Meeting on Evaluation of Pandemic Influenza Prototype Vaccines in Clinical Trials to be held by the World Health Organization (WHO) in February of 2009.

Based on these results, we are planning the launch of Phase II clinical trials later this year. UMN might increase the quantity of antigen administered in order to improve immunogenicity.

Shuichi Kanazashi, the President and Chief Executive Officer of UMN Pharma Inc., commented: "The results of the Phase I/II clinical trials confirmed the efficacy and high safety of UMN-0501. We will soon conduct a clinical trial with an increased quantity of antigen and expect to obtain good results that meet the international standards for approval. Amid concerns over the crisis of a pandemic influenza outbreak, we will faithfully advance UMN-0501 through clinical trials 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 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.

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.

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