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For Immediate Release

UMN Pharma, Inc.

## **API and UMN Pharma Announce Formulation Process Collaboration**

### **- Comprehensive Alliance Focused on Formulation Process of UMN's Influenza Vaccine -**

UMN Pharma Inc. (headquartered in Akita, President & CEO: Shu-Ichi Kanazashi, M.D., Ph.D.) and API Co., Ltd. (headquartered in Gifu, CEO: Takahiko Nonogaki) today announced that the two companies have signed an agreement forming a comprehensive business alliance focused on the formulation process of UMN-0501\*<sup>1</sup>, UMN Pharma's influenza vaccine, manufactured using cell-culture.

UMN Pharma and API view this alliance as a collaboration that will ensure an opportunity to learn technical information and develop expertise together. The companies will work together closely to establish the optimal formulation process and in the preparation of formulation facilities. In the future, UMN Pharma will entrust vaccine formulation to API.

UMN Pharma initiated a Phase II clinical trial last October for the development of a recombinant influenza HA vaccine (H5N1 strain), UMN-0501, which is manufactured through cell culture using a baculovirus expression vector system. UMN Pharma is in the process of finalizing the Clinical Study Report for the Phase II clinical trial. Using the baculovirus expression vector system to produce protein via cell culture represents a large improvement over traditional egg-based production methods that can take six months or longer to yield product. Through the use of the baculovirus system, UMN-0501 can be produced in only two months. In addition, the use of this cell culture system allows for a larger protein yield meaning that UMN Pharma can provide a large amount of vaccine. Importantly, this expression system allows UMN Pharma to completely avoid the use of live influenza virus.

Shu-Ichi Kanazashi, the President and Chief Executive Officer of UMN Pharma Inc., comments that "This partnership with API allows UMN Pharma to provide finished drug substance to the market for our influenza vaccine manufactured in collaboration with IHI Corporation. Our influenza vaccine will be shipped from API's IKEDA Pharmaceutical Factory which has a great deal of experience in the commissioned manufacturing of drug product. UMN Pharma's



collaboration with API will allow for the quick and large scale production of our influenza vaccine, thus enabling UMN Pharma to rapidly address Japan's influenza vaccine needs including preparedness for a highly-pathogenic avian influenza\*<sup>2</sup> H5N1."

Takahiko Nonogaki, the Chief Executive Officer of API Co., Ltd., comments that "It's really an honor to collaborate with UMN Pharma because this partnership is the first step in all contribution to the improvement of public health. We will build a facility for the formulation of UMN Pharma's vaccine and will ensure a stable vaccine supply to the market as quick as possible as our mission in cooperation with UMN Pharma".

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\*<sup>3</sup>. The tolerability of UMN-0501 was good with no serious or highly adverse side effects diagnosed by the principal investigator.

\*2 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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### **About API Co., Ltd.**

API Co., Ltd. was founded in 1907 as a company dedicated to harmonize with nature and human being through honeybee and create much health life. We expanded our business from the beekeeping business to the contract manufacturing for dietary supplements and have started contract manufacturing for pharmaceuticals in 2004. Our current pharmaceutical plant, we are manufacturing injectable cephem and carbapenem antibiotics.

Foundation: October, 1972 (Founded in 1907)

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