Industry Watch
JAPAN

Japan’s Bioventures Today —

UMN Pharma Inc

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Background of UMN Pharma
UMN Pharma Inc (UMN Pharma) is a venture company dedicated to developing innovative pharmaceutical products that address unmet medical needs — and hence, the name of the company. In Japan, there are many drug candidates that are being developed at various academic and research institutions. However, only a small number are licensed by pharmaceutical companies in Japan. Established in April 2004, UMN Pharma aims to bridge the gap between scientists, academia and bioventure companies that develop potential drugs in the early stages of development, with leading pharmaceutical companies that typically prefer to obtain licenses to potential drugs in the later stages of the development.

Business of UMN Pharma
UMN Pharma’s business concept is to obtain licenses to potential pharmaceutical products from scientists, universities and other companies while they are still in the early stages of development. After conducting preclinical and early stage clinical trials internally, UMN Pharma will then license them to pharmaceutical companies.

Fig. 1 UMN Pharma’s business model.
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Through this effort, the company aims to add value to potential drugs that treat diseases with unmet medical needs and to improve the efficiency and productivity of the entire development process.

One of the most vital components to the success of this business model is the careful selection of the most promising technologies and products for further development. UMN Pharma’s board of directors and management team consists of personnel with extensive experience and expertise in the area of drug research and development. They have working experience in the pharmaceutical companies and renowned academic institutions. Some of them are medical doctors with strong expertise in clinical patient care. Thus, the team at UMN Pharma is in touch with the latest industry trends as well as academic directions. It also has a wide network including academia, medical institutions and pharmaceutical companies that are essential to the development of new drugs. One of the core strengths of the company is its ability to accurately assess the potential of new products or technologies, and also its ability to assess the marketability and risks of new products.

**Project Pipelines of UMN Pharma**

UMN Pharma currently focuses on five major areas; cancer, pancreatitis, muscular dystrophy, diabetes and influenza.

**Anticancer Agent (UMN-01)**

UMN-01 is a small molecule down-regulator of GRP78, which is a glucose regulated protein. It is known that an unfolded protein response caused by glucose deprivation is observed in solid tumor cells. GRP78 plays a primary role in the unfolded protein response, and thus its expression increases in the tumor cells. In addition, a study observed that an increase in the

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**Fig. 2** UMN Pharma’s project status.
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expression of GRP78 occurs when anticancer agents such as cisplatin are administered to cancer cells and resistance occurs. This result is due to the apoptosis inhibitory effects of GRP78. By targeting and regulating GRP78 selectively, UMN-01 is able to minimize adverse effects while demonstrating a high level of efficacy on cancer cells even when tolerance to the existing anticancer agents has occurred. UMN-01 is currently undergoing preclinical trials and its first clinical study is planned to commence in 2008.

A number of studies have been conducted on GRP78 as a new cancer therapeutic target over the course of the past 10 years. However, there has yet to be a single product capable of regulating the expression of GRP78.

**Pancreatitis Therapeutic (UMN-02)**

In Japan, only proteolytic inhibitors are currently approved for the treatment of pancreatitis, and there is no approved drug outside Japan. Therefore, there is a high demand for drugs that treat pancreatitis as the efficacy of the existing drugs is not satisfactory. UMN-02 has been developed from the company’s own research. UMN Pharma’s researchers found that certain types of neurotransmitter receptors were closely related to the onset of pancreatitis. It has successfully identified an existing drug that has a potential to become a treatment for pancreatitis. UMN Pharma has filed the necessary intellectual property rights of the drug to redevelop it as a therapeutic drug for pancreatitis. The company is conducting some exploratory clinical studies in Japan.

The major drugs to treat pancreatitis currently available in the Japanese market are gabexate mesilate (FOY®) and camostat mesilate (Foipan®), developed by Ono Pharmaceutical Co Ltd, urinastatin (Miraclid) developed by Mochida Pharmaceutical Co Ltd and nafamostat mesilate (Futhan injectable) developed by Torii Pharmaceutical Co Ltd. These drugs had total sales of approximately 40 billion yen in 2005.

**Muscular Dystrophy and Diabetes Therapeutic (UMN-03)**

UMN-03 is a recombinant fusion protein that neutralizes the function of endogenous myostatin, which is a growth and differentiation factor 8 or GDF-8. Myostatin is known for reducing the amount of muscle tissue by suppressing the differentiation of myoblast cells. Early studies demonstrated that a crossbreed of mice with muscular dystrophy and mice lacking myostatin had significant improvement in the volume and function of the muscle. In addition, myostatin neutralization from the body is found to be also effective in reducing fat tissue, thus providing a new therapeutic approach for obesity and type II diabetes. UMN Pharma is manufacturing UMN-03 at a contract manufacturing organization for preclinical and clinical studies.

Muscular dystrophy is one of the illnesses with the most critical unmet medical needs. Although there are several potential drugs in the clinical stages of development, there is no
drug specifically for the treatment of muscular dystrophy yet.

Influenza Vaccine (UMN-05)
UMN Pharma has obtained exclusive rights to develop, manufacture and market an influenza vaccine in Japan. This vaccine is currently being developed by Protein Sciences Corporation under the trade name of Flublok™ in the US. With this license, UMN Pharma is currently developing UMN-05 for two recombinant vaccines, trivalent inactivated influenza vaccine and a vaccine against avian influenza virus. UMN-05 is a recombinant hemagglutinin (HA) protein influenza vaccine produced in special insect cell lines and formulated in phosphate buffered saline without any preservatives or adjuvant. The new technique of producing the vaccine using UMN-05 allows for the production in about one-sixth of time required by the conventional method. In addition, the vaccine readily caters to new types of influenza. Also, the use of RNA extracted from the inactivated virus for the production of vaccine assures safety and high efficacy of the vaccine. UMN Pharma is targeting to start its first clinical study of this vaccine in the first quarter of 2008.

The total sale of influenza vaccines produced by the four major manufacturers in Japan was approximately 17 billion yen in 2004, which is equivalent to the dosage given for about 30% of the Japanese population. The Health, Labor and Welfare Ministry in Japan is making an effort to improve the immunization rate, thus the sale of influenza vaccines is expected to double in the future.

Future of UMN Pharma
With its experienced management team; wide network that spans the pharmaceutical industry, academic institutions and investment community; and promising pipelines, UMN Pharma strives to continue its effort to accelerate the development of innovative pharmaceutical products that address the unmet medical needs of patients.